

## **BIOTEST AG**

**DECLARATION OF COMPLIANCE  
WITH THE GERMAN SUSTAINABILITY CODE (DNK) /  
NON-FINANCIAL DECLARATION  
PURSUANT TO SECTION 289 HGB  
[GERMAN COMMERCIAL CODE]**

**FINANCIAL YEAR 2019**

Reporting standard: DNK EFFAS

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## Preliminary remarks

For the first time in 2018, Biotest AG submitted a declaration of compliance with the sustainability code / a non-financial declaration. However, given the company's exceptional corporate responsibility ethic, sustainability has been embedded in its business model, value creation structure and products since it was founded. Our close stakeholders are well aware of this, and we are now taking advantage of the reporting requirement to demonstrate Biotest's sustainable business model and business purpose to a wider public. Due to current changes in the Group structure, unless otherwise stated, the environment key figures relate to the Biotest AG entity in Dreieich, Germany, and not the Group. This is for the sake of better future comparability. Outside the Dreieich site, there are 8 foreign sales subsidiaries and 3 plasma collection subsidiaries in the Biotest Group.

Measured by the legal materiality criteria for reporting on non-financial risks - after implementing risk mitigation measures - no material risks have been identified.

For ease of reading, we refrain from using both masculine and feminine pronouns when referencing individuals and groups. However, words and pronouns referring to one gender also refer to all genders.

The Supervisory Board of Biotest AG has examined and approved the Declaration of Compliance presented here. An external review and confirmation of the information has been carried out by Mazars GmbH & Co. KG Wirtschaftsprüfungsgesellschaft Steuerberatungsgesellschaft.

## General

Biotest AG is an international supplier of biological medications. These are obtained from human blood plasma. Its main fields of application are in haematology, clinical immunology and intensive care medicine. The company's operations are divided into the following segments: Therapy, Plasma & Services and Other Segments.

Biotest covers the entire value chain for manufacturing of plasma proteins, from collection of blood plasma, processing into medications to sales. The company's headquarters and manufacturing are located in Dreieich. Biotest is present in around 90 countries with its own sales subsidiaries and via local distribution partners. More than 1,930 people are employed worldwide, and Group sales registered €419 million in financial year 2019 for continuing operations.

The impact of our business activities on our environment is immediate, and they are positive because Biotest produces essential medications for the critically and chronically ill. We are thus creating a new outlook for these individuals with trend-setting research and innovative products. Moreover, these products are based on human blood plasma as a natural and replicating raw material. Neither the further processing nor the delivery/marketing of the final products are associated with significant adverse effects on the environment. Our value chain is

highly regulated by a large number of external and voluntary standards, and it is continuously monitored in the same way. Equally, we can also exclude forced and child labour or other exploitation here. The blood plasma is a voluntarily donated raw material from healthy, specially qualified donors.

## Strategy

### Strategic analysis and measures

1. The company describes its analysis of the opportunities and risks for its key activities with respect to sustainable development. The company explains the concrete measures it is taking to operate in alignment with major applicable industry, national and international standards.

Global megatrends not only create risks, but also open up opportunities for us. We use our expertise and innovative capacity to take advantage of these opportunities and contribute to overcoming global challenges.

A steadily growing and ageing global population requires new and better medications. With an expanding population, the number of people suffering from serious and chronic diseases is also growing, and we manufacture essential medications for certain indication areas. Well over one billion people have no access to necessary medications, because adequate or affordable healthcare is unavailable in many regions. Initiatives in these countries, e.g., breaking down access barriers with pro bono supplies, are effective responses to these challenges.

As an international company, we are also subject to ethical, economic and legal risks that we must constantly work to minimise. We are committed to complying with legal and ethical standards in our interactions with suppliers and other business partners around the world. We have created the necessary structures and systems to achieve this. Our environmental management is designed to minimise even further the already low environmental impacts of our business activities. For our employees we are an honest and attractive employer.

We need to ensure our economic management is sustainable and that we are taking our business activities in a sustainable direction to ensure our company is future-proof. Our goal is to ensure our business success by aligning it with societal and ecological requirements, to raise our company's value.

Responsible corporate governance forms the foundation for this approach, and opportunity and risk management is an integral component of our company management. To this end, we have established processes and structures to systematically recognise and seize opportunities, and to avoid risks that threaten our business success.

As part of our strategy and planning processes, we pay close attention to relevant external and internal challenges, analyse economic, environmental and social developments, extrapolate

trends and observe macroeconomic and industry circumstances, to identify opportunities and scope for development for Biotest.

Biotest also expressly supports the comprehensive approach of the United Nations Sustainable Development Goals (SDGs) for 2030. In particular, we support the goals for good healthcare (SDG 3) throughout the world with our core business. The other SDGs are also addressed by our internal requirements supporting corporate social responsibility.

Biotest's sustainability report is based on the ten principles of the United Nations Global Compact (UNGC), as well as other international guidelines and recommendations, including for the definition and selection of non-financial indicators and for reporting, such as those of the OECD. The recommendations of the 'European Federation of Financial Analysts Societies (EFFAS)' are taken into consideration when selecting and measuring indicators.

Our sustainability report follows the guidelines, the structure and the proposed criteria selection of the German Sustainability Code (DNK), also documented by the Declaration of Compliance under the DNK standard as submitted here.

## Substantiality

2. [The company indicates which aspects of sustainability have a substantial influence on its business, and how it integrates these into its strategy and systematically addresses them.](#)

Biotest produces biological medications that are derived from human blood plasma. This plasma is provided by healthy people, who want to help ill people – the donors do not sell it, they donate it and only receive an allowance. They do so out of personal conviction, on their own initiative, and in confidentiality, to make a vital contribution to others who are less fortunate. Their plasma donations offer fellow human beings a chance of survival, or improve the quality of life and extend the life expectancy of people with chronic diseases. Need for plasma proteins can be very high – for example, a person suffering from haemophilia monthly relies on plasma proteins, which are derived from up to 100 plasma donations.

In some 90 countries around the world such patients rely on our help and the quality and efficacy of our medications.

Producing medications that rely on voluntary donation of a scarce human raw materials, with the goal of offering live-saving benefit to seriously ill people, makes our business highly responsible in its very essence. This responsibility to donors and seriously ill patients and our value creation structure and mission are at the heart of what sustainability means for us.

The exceptional responsibility that Biotest holds here with respect to donors, their donations and patients, characterises the claim and intent of our sustainability strategy –

## **TAKING RESPONSIBILITY.**

Hence, we have thoroughly analysed our value chain links and processes regarding their sustainability impact with the result: all our actions to protect donors, their donations and patients are key features of our sustainability approach. All activities and processes in the entire value chain that are related to protection, safety and quality are therefore relevant to our sustainability strategy.

We mean by this not only the direct protection of donors and patients, careful management of plasma and the effort to gain maximal yield and as many products as possible from this scarce raw material. All measures to support our medications' efficacy, ensure good tolerability and eliminate side effects are also components of sustainability.

Our responsibility takes concrete form in several areas:

### **Responsibility towards patients and users**

Biotest works in a highly regulated environment in which drug safety and quality are the top priorities. We comply with this environment by following strict safety standards that far exceed the legal requirements, and comprise two central aims: Ensuring safety and quality in all the research, development and manufacturing phases for our products, and producing medications that set benchmarks for safety, quality, tolerability and user friendliness.

These goals are operationalised in the form of a rigorous zero-error tolerance with respect to the health of plasma donors, plasma donations and the final product, otherwise contaminated plasma could cause severe infections of patients.

If doubt arises at any point as to the safety of a donor, indications concerning the quality of plasma or any other possible concerns about the final product, we respond immediately and systematically. For example, if a donor is found to be infected with HIV, hepatitis or parvovirus B19 subsequent to a donation, not only is he excluded from further donation, but all plasma in storage is destroyed.

Concerning our responsibility towards patients, we do not differentiate based on the countries they live in or whether less restrictive or less costly standards would apply than at our headquarters – we serve all patients under identical safety standards which are the highest applicable here in Germany.

### **Responsibility towards our donors**

Well known is the system of the obligation to report side effects for medicinal products - the so-called "pharmacovigilance". However, we are just as much interested in our donors' wellbeing both during and after donation. As part of the "haemovigilance" system, side effects and unusual reactions during the donation are recorded and evaluated.

Haemovigilance is a systematic monitoring system mainly to ensure the donor's well-being but also to continuously monitor and improve the donation process itself. Preventive protective measures have top priority for the donor; the goal for the donation process is the early detection of new risks and quality deficiencies while plasma donation.

Our donors should feel safe and should want to return. We take our responsibility for our donors very seriously.

### **Responsibility towards our employees**

Our responsibility towards our employees has been translated into various individual goals and supported with multiple actions. We create the conditions for our employees to work independently, with a high level of accountability and in teams with very skilled and motivated co-workers. We seek out creative thinkers who crave challenging tasks, and offer in exchange varied occupations, space for personal development and manifold promotion opportunities. Biotest takes its responsibility as an employer seriously. Biotest combines the benefits of a dynamic medium-size business with advantages that are otherwise generally only found in large corporations. Biotest's culture is as international as a corporation and as personal as a medium-size company.

These goals are realised via a variety of on- and off-the-job training measures and diverse further education programmes, so that our employees are able to develop and evolve in accordance with their abilities and desires. We create a scope for development and collaboration with flat hierarchies and short decision pathways. We support work-life balance in part with our in-house childcare known as BioNest. Last but not least, our responsibility towards our employees is apparent in our very attractive social and financial benefits (see criterion 16).

### **Responsibility for young people**

Based on detailed planning of company needs, Biotest ensures that there will be an ongoing job afterwards for all apprentices. We inform pupils of the apprenticeships offered by Biotest, organise open days and creation labs for secondary school and college students, and offer targeted orientation events.

Due to our close cooperation with universities, we are not just represented at job fairs and arrange regular information days and production site tours. We also sponsor professional Bachelor's and Master's courses and offer graduates international trainee programmes.

We not only accept responsibility for youth, but also for our employees' children. Because in our BioNest childcare centre we ensure intensive and individualised care for children with above-average carer ratios.



## **Responsibility towards investors**

As a public company listed on the stock exchange, we have a financial responsibility to our shareholders. This includes the careful use of financial resources, sustainable and long-term management as well as transparent and timely information on all important and, if necessary, short-term developments in the company and its markets. These goals are operationalised with a system of objectives comprising value creation, profitability, inventory management and other targets, and which is partially tied into the remuneration system.

## **Responsibility in the world**

Providing adequate medical care and treatment with plasma proteins to people, viewed from a global perspective, is more the exception than the rule. For example, around 75% of the patients suffering from haemophilia A have no or insufficient access to appropriate treatment. Biotest accepts this responsibility.

We are the co-initiators of 'Project Recovery', along with the World Federation of Haemophilia (WFH), aiming to provide free medications for patients in developing countries (currently inactive). We also support the Global Alliance for Progress (GAP), a WFH programme aiming to improve diagnosis and treatment of haemophilia patients in countries with a shortage of medical treatment. Thus far, this project has considerably improved the status of over 40,000 patients in 33 countries.

And, last but not least, we also have a responsibility towards the healthcare system – which we seek to support not only with the safety and quality of our medications, but also by developing dosage forms that can reduce the amount of doctor appointments, so as to reduce cost burdens on medical payment systems through self-medication, for example.

Our materiality analysis is based on a close exchange with our stakeholders. Further sustainability chances and risks are described in criteria 1 and 3.

## **Goals**

3. **The company describes which qualitative and/or quantitative and time-delineated sustainability goals are defined and operationalised, and how their progress is measured.**

The term “sustainability” does not have a single definition. However, in the interest of simplicity its various concepts can be traced back to a common denominator. Despite the many different definitions that may be used in sustainability discussions, what is fundamentally at stake is our responsibility for future generations and their quality of life, and how our actions today contribute to these goals.



Our central sustainability goals are to take responsibility and to live up to this as effectively as possible. And we do not just accept this responsibility for future generations. We take on such responsibility today by offering people with serious diseases a chance of survival and trying to improve the quality of life of people with chronic illnesses as best we can. Also because blood plasma is a natural and replicating raw material, and no significant environmental damage is caused by our production processes, our activities and use of resources and our business will not be a burden on future generations.

'Taking responsibility' is not only the central guiding principle for Biotest, but it also represents the overarching concept and frame of reference for our sustainability management. Accordingly, this concept is designed in several dimensions and transformed into individual goals.

This not only applies to specific objectives for key stakeholders such as patients, employees and owners, but also includes key sustainability issues such as the environment, resource use and compliance with external (e.g., legislation) and internal standards (e.g., process safety, zero-error tolerance).

Wherever possible and meaningful, these subject areas and sub goals are further specified and operationalised by key figures, in order to communicate expectations more transparently and to be able to make a clearer assessments of achievements or targets (see also the remarks and goals concerning energy use, waste generation, plasma yield and emissions in criteria 10-13). In other cases, these objectives are contained in standards and procedures (for example, in the Compliance Manual).

Controlling and monitoring of the achievement of objectives are just as dependent on the individual case as the frequency of the review and the involvement of the top management. The context in which the reporting on this takes place is equally dependent on the individual case. While reporting and the discussion of financial and performance issues predominantly take place in board meetings as part of monthly reporting, department-specific projects and initiatives that do not address the full board are managed through project and departmental meetings.

In addition, topics with a particular risk potential are also included in the risk management system. Approximately 120 short-term and 80 long-term individual risks are currently monitored by the risk manager and the risk management committee, and reporting takes place on an ad hoc basis, at the latest every six months. There are also numerous sustainability-related topics represented here, such as risks and their probability of occurrence, impact class and coping strategy with regard to surroundings, environment, employees, supply chain and law/legislation. Given that many things are not avoidable but always controllable for Biotest, we are working on an even closer integration of sustainability management and risk management. This is because we consider the inclusion/assessment of longer-term trends and changes in the environment in our risk management as an opportunity to use this more effectively as an early-warning system and to be able to further increase the effectiveness of our sustainability management simultaneously.

Ensuring maximum product and process safety is a priority objective for Biotest. Since further sustainability goals may well lead to conflicting objectives, we do not prioritise nor favour one goal at the expense of another, but strive for their achievement at the same time.

A unique factor in terms of sustainability at Biotest, however, is that growth does not represent a waste of resources at the expense of present or future generations. Because, on the one hand, the main resource used, blood plasma, is able to regenerate, i.e., it is a 'renewable raw material'. On the other hand, growth of our company means that we were able to reach and supply even more seriously and chronically ill patients. Consequently, our growth targets do not stand in the way of the sustainability goals; they are more congruent and work in the same direction.

### Depth of the value chain

#### 4. The company indicates the significance of aspects of sustainability for value creation, and the depth to which sustainability criteria are verified in its value chain.

“Taking responsibility” is our central sustainability goal. It characterises our identity and our actions. We have also applied this guiding principle in designing our value chain. All processes are shaped to support the best possible protection for donors and patients, and to maximise safety. Accordingly, a close-knit web of controls, quality assurance processes and other precautions governs our entire value chain, from plasma donation to delivery of the medications we produce, to best ensure our responsibility towards our donors, donated plasma and patient. Our value chain is therefore designed as follows:

**Procurement:** Given the complexity of dealing with plasma derivatives and the associated need to procure plasma as the sole raw material, we have set up our own plasma purchasing department. There, suppliers are managed internally and externally to meet the exacting requirements of the plasma and its donors.

All plasma suppliers, together with the countries of origin, plasma stores and plasma test laboratories, are audited by Biotest and approved by the European Medicines Agency in the so-called Plasma Master File (PMF) process. We use PMF plasma exclusively.

We usually obtain plasma frozen at a minimum of -20°C. This is donated voluntarily, either as part of a blood donation, whereby the cellular components are separated from plasma after the donation ('recovered plasma') or by automatic plasmapheresis, whereby the donor receives his cellular components back during the donation. According to the European Pharmacopoeia, the plasma must be deep frozen under validated conditions within 24 hours at the latest after it is obtained, reaching a core temperature of -25°C within 12 hours at the latest.

Every plasma donation is tested serologically for anti-HBsAg (HBV surface antigen), anti-HCV (hepatitis C virus) and anti-HIV1/2 (human immunodeficiency virus). In addition, each plasma donation undergoes NAT testing (Nucleic Acid Testing) in a so-called minipool for the following

viruses: hepatitis A virus (HAV), hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV) and fifth disease (parvo B19).

As a member of the PPTA, Biotest performs more testings than the statutory requirement. The requirements for plasma are very strict under PPTA QSEAL certification and the associated binding IQPP specifications, see also

<https://www.pptaglobal.org/safety-quality/standards/qseal>

<https://www.pptadeutschland.de/qualitaet-sicherheit/qualitaetstandards/iqpp>

In principle, only healthy people from certain geographic areas are allowed to donate (even a holiday in contaminated areas such as Kenya or Great Britain is a reason for being rejected from donating), have certain habits and customs (no drug abuse) and are verifiably doing so of their own free will (after every donation, the donor is free to withdraw, for example if he has been subject to peer pressure).

The donation and treatment processes include further measures to ensure safety and quality:

**Reception of plasma donors:** Donors confirm their identification with their donor or picture ID. They must reside permanently within a defined distance from the donation centre and be between the ages of 18 and 65. Donors who have a cold, recent tattoos, specific previous illnesses, travel to defined regions, etc. are excluded. In addition, a questionnaire on his state of health and his risk group assessment as well as a vital sign test (blood pressure, pulse, body temperature, haemoglobin) must be completed. Each donor also undergoes a medical examination.

**Medical examination:** Once this information is collected and compared to a blacklist, a medical examination is required at regular intervals to certify donor safety. The physician determines the person's suitability as a donor, with a typical exclusion rate of around 20% in Germany.

**Extraction:** Before the donation and after identity verification, the donation process is explained. Blood is extracted to the plasmapheresis device, where plasma is separated from the other blood components. The plasma is collected, while the blood cells flow back into the donor's body. Plasma can therefore be donated more often than blood, as the body can reform plasma within a few days. Following the donation, donors can receive an expense allowance in accordance with legal regulations. For the integrity of the plasma ingredients, the plasma is frozen, and storage and transport are kept at -20° Celsius any time.

**Reception:** To ensure the quality and safety of the medications, Biotest exclusively collects the plasma under controlled temperatures at plasma centres.

We inspect each incoming donation for quality and integrity in line with Biotest requirements in the incoming goods inspection. Every donation is received individually and can be traced back from the end product to the donation for a period of 30 years.

**Production:** Plasma is processed by pooling and thawing thousands of donations in a so-called plasma pool. This plasma pooled is tested for HIV, hepatitis and parvovirus B19 markers.

Positive pools are destroyed. The different fractions of the plasma that constitute the raw material for an end product are separated by fractionation using variations in alcohol content, temperature and pH value, and numerous additional processing steps then yield clotting factors, immunoglobulins and albumin. Multiple stages of filtration, depletion and pasteurisation are then carried out to deactivate and eliminate viruses and thrombogenic factors, and to reduce prions to ensure the final product is as safe as possible.

The full manufacturing process from plasma donation to delivery of the medication lasts around seven to eight months. Final release of the products follows – separately for each batch produced – in Germany by the Paul Ehrlich Institute.

To meet our responsibility to patients for maximum product safety and quality, close communication and cooperation along the value chain is necessary but not enough alone. Therefore, we have extended our expectations and requirements to our business partners (as stated above) in strict and detailed guidelines and standards. This allows us to ensure that the behaviour and actions of our business partners are in line with our sustainability goals, especially as compliance with these guidelines is closely monitored by Biotest and, in part, by external bodies.

## Process Management

### Responsibility

#### 5. Executive governance responsibilities for sustainability are described.

Responsibility for the sustainability management lies with the Biotest AG Board of Management, with assignment of specific individual topics corresponding to the relevant area of responsibility. The Supervisory Board is provided regularly with a report on the status and progress. Supervision and reporting for specific sustainability issues is either part of regular management reporting or addressed in separate project meetings.

Sustainability at Biotest concerns and applies to everybody – every employee is responsible for it within the framework of their own work and capabilities. The 'Klimaretter-Lebensretter' (Climate Savers – Lifesavers) project, for example, shows how this is embraced.

Taking the stairs instead of the lift, not leaving appliances on standby, using the heating properly, eating less meat, and many more measures! Biotest, together with other companies in the health sector, is taking part in this project whereby employees volunteer to help make their workplace more environmentally friendly. Individual actions relating to energy, mobility and consumption can be selected from 23 predefined measures and implemented for a time period chosen by the participant. This commitment to the environment can be seen directly via a CO<sub>2</sub> calculation, and the 72 participating companies are continuously ranked in terms of their impact reduction, which provides another incentive.

This ensures that even small measures, when they are implemented by multiple 'climate savers', can make a big difference to the planet. Three months after the start of the project at the end of October 2019, employees in 30 different department groups are volunteering here, the results of which can be compared on the Internet as an incentive, and this figure keeps on growing. Biotest is currently ranked 12<sup>th</sup> out of all the participating companies, with a total saving of 8,052 kg of CO<sub>2</sub>.

And, we as a company are continuing to work on such small yet, in their totality, effective measures in order to be able to further reduce our carbon footprint. For example, in 2019 we removed single-use cups from our coffee machines; we want to transition quickly to reusable containers for water and soft drinks; processes that have used paper until now (e.g., the compliance approval process in 2020) will be converted onto a paperless SharePoint algorithm; pens used for marketing purposes are now made of sustainable plastic as they are produced from renewable and compostable sugar cane; we purchase from a PC manufacturer that makes its housings primarily from recycled plastic from old computers and has processed almost 10,000 tonnes of old plastic for this purpose.

Last but not least, we provide our employees with the appropriate tools so that they can make contributions to protecting the environment - for example, with Skype for business in order to be able to replace traveling to meetings and conversations with similarly effective online communication, or with a software-based option for prioritizing procurement goods in order to bundle less urgent and C goods at a supplier and thus reduce the number of deliveries.

## Rules and processes

### 6. The company describes how the sustainability strategy is implemented using operational business rules and processes.

In striving to do business sustainably, Biotest does not rely only on compliance with applicable laws and external regulations. We also adopt voluntary requirements and standards, such as with respect to plasma and donor safety.

These standards allow us to meet internationally recognised ethical, social and ecological principles of corporate management, and to integrate these concretely into our business processes. Additional concrete guidelines are implemented in various central areas such as Compliance, Purchasing, HR, Waste/Disposal, as well as the Environment, Health & Safety Policy (EHS).

We have also developed clear guidelines and frameworks with respect to our employees' conduct – not just to orient our team members, but to anchor sustainability standards in our work processes. Our comprehensive Code of Ethics and Business Conduct is of particular importance here, providing employees with some 30 pages of clear guidance. This document explicitly lays out expectations of behaviour, as well as the consequences of lack of compliance

by an employee or tolerance by a supervisor. Participation in training on the Code of Ethics and Business Conduct is not only compulsory for employees and executives, the training has also to be repeated every 3 years.

These group guidelines apply across the organisation and into the supply chain where possible, even if supply does not lie directly within Biotest's area of control. Our corporate guidelines are directive in nature, and are continuously monitored to respond to changes in background conditions or stakeholder requirements.

In addition, we have established processes to implement this strategy operationally using a variety of sustainability-related performance indicators (see criterion 7).

In the last two years, both organisational changes and staff increases have been implemented to make our sustainability management even more effective. The areas of occupational safety, energy management and environmental protection were merged into the newly created EHS (Environment, Health and Safety) department. Since the energy management has already been certified since 2014, we are currently working in the field of occupational safety on the certification with seal of quality of the BG RCI (Trade Association Raw Materials and Chemical Industry). In the medium term, we also strive for the introduction and certification of an integrated management system.

## Control

7. The company describes how and which sustainability performance indicators are used in regular internal planning and control. It illustrates how appropriate processes ensure the reliability, comparability and consistency of data for internal management and external communication.

In addition to energy-related indicators such as energy consumption per litre of plasma processed, the share of renewable energies in electricity purchases and waste management key figures, Biotest uses a large number of other performance indicators to manage its business and sustainability performance. It clearly defines for each indicator, how and at what rhythm it should be measured or reported, i.e. weekly, monthly, quarterly or annually. For each indicator, it is also determined at what level of the company and as part of what management process it is to be measured, i.e. whether it is a component of regular reporting and control processes (e.g. financial and HR indicators) or is monitored as part of specific or thematic project (e.g. R&D projects; the Biotest Next Level expansion project; energy management; waste management).

Many of these indicators are also a permanent component of our financial and business reports, in particular with respect to finances, research & development and HR.

All EFFAS (European Federation of Financial Analysts Societies) sustainability indicators used in this Declaration of Compliance are a core part of our controlling processes. The indicators used



by Biotest for direct and indirect management of our sustainability performance far exceed the number of EFFAS criteria.

**EFFAS S06 - 01 performance indicator:**

**Share of suppliers and partners in the supply chain who are assessed for compliance with ESG criteria.**

0% because not relevant to sustainability performance.

**EFFAS S06-02 performance indicator:**

**Share of suppliers and partners in the supply chain who are audited for compliance with ESG criteria.**

0% because not relevant to sustainability performance.

As a manufacturer of medications and due to its use of blood plasma, a potentially infectious material, Biotest operates in a highly regulated environment. The entire value chain through to the patient is subject to strict and uninterrupted monitoring by various authorities and organisations. In some cases, very few suppliers are approved by authorities, in extreme cases only one supplier is certified worldwide for a given product (e.g. special filters for production). In these cases, assessment and auditing of suppliers would be conceivable, but changing suppliers if deviations from ESG (environmental, social, governance) criteria were found would, however, not be possible.

Therefore, no assessments or audits of our suppliers using ESG criteria are performed. Due to our procurement guidelines (local/Western Europe focus) and order bundling with large, capable suppliers located here (also see criterion 17), we can largely exclude any ESG-related issues within our value chain.

**Incentive systems**

8. The company describes how performance targets and remuneration for management and employees also align with sustainability goals and long-term value creation. It shows to what extent reaching these objectives is a component of performance evaluation for the highest level of executive management (Board of Management/Executive Board) by supervisory bodies (Supervisory Board/Advisory Board).

The incentive system for management at Biotest is based on agreements around company goals, and goal achievement determines the amount of variable remuneration.

The Supervisory Board defines corporate goals for the Board of Management and defines for each board member's area of responsibility how a given result translates into a percentage



achievement of the relevant goal. The Supervisory Board also defines specific quantitative and/or qualitative goals individually for members of the board, which can also involve sustainability performance. At the end of each financial year, the Supervisory Board verifies whether or to what extent these goals were met.

The Biotest management system also encompasses performance goals for non-pay scale employees. Employee variable remuneration is aligned with the profitability and operational efficiency of the company as a whole.

Goals are not differentiated based on their relevance to sustainability. Since the essence of our business model is sustainably focused on responsibility to donors, patients and the environment, our performance-based remuneration systems indirectly have a positive effect on sustainability performance.

### **Stakeholder participation**

9. The company describes how social and economic stakeholders are identified and integrated into the sustainability process. It indicates whether and how ongoing dialogue with stakeholders is supported, and the results integrated into the sustainability process.

We maintain regular contact with the people and groups whom we impact with our decisions and activities, or who have influence over our business. Our stakeholders include, for example, our employees, business partners, shareholders and other investors, analysts, physicians, patients, patient organisations, public authorities, associations and neighbours to our sites. We conduct stakeholder dialogue around specific topics as need arises. Systematically structured stakeholder identification or consultation to determine which aspects of sustainability appear most relevant to them has not so far taken place. However, because we are in close and regular discussion with our stakeholders, we assume that key topics and demands are addressed in this way.

As part of our usual business activity, our specialist departments generally organise direct dialogue with stakeholders at local, national or international level depending on the topic and significance and conduct this in the form of one-to-one discussions, workshops or seminars, or as part of large conferences. Biotest is also engaged in industry networks and takes part in trade conferences and trade fairs.

### **Innovation and product management**

10. The company describes how it uses suitable processes to ensure that product and service innovations contribute to improving sustainability of its own use of resources and that of users. It also indicates whether and how the current and future impact of its key products and services in the value chain and product life cycle is evaluated.

The focus on our innovation efforts centres on saving lives, improving the quality of life of people with chronic diseases, and ensuring the greatest possible product safety while doing so. Protection of resources is another key sustainability aspect of this approach. We are therefore committed to utilising donated plasma as effectively as possible on behalf of the donors, and continuously improving efficacy and yield.

It is the nature of our business to work directly with patients, patient organisations, universities, physicians, hospitals and clinical trials, so that we are closely involved in the use, handling and effect of our products. Our direct connection to the actual use of our medications as well as the treating physicians allows us to carefully target our improvement potential and our innovation policy. This proximity and our own holistic development approach was, for example, the driver behind the development of Zutectra, the worldwide first medication that a patient could inject themselves under the skin following a liver transplant to prevent re-infection with hepatitis B. These patients are not only spared many doctor and clinic visits, but also gain considerable autonomy, freedom and quality of life. We have achieved a similar increase in user-friendliness by halving the intravenous volume of the coagulation factor preparation Haemoctin, which also significantly reduces the treatment burden for the patient.

With Biotest Next Level, the largest investment project in our company's history, we will be able to produce five instead of three products from the same volume of raw material and significantly increase the plasma yield, which represents a quantum leap in our innovation and sustainability performance. This new facility will meet the requirements of both European and US regulatory authorities and will allow Biotest to distribute the products manufactured there worldwide.

Trimodulin is one of the additional products from the new production facility for the treatment of severe community-acquired pneumonia, which is often fatal. Phase II results suggest that the mortality rate of such patients can be more than halved. Equally encouraging are the available results for the fibrinogen product BT-524, which is in Phase III and helps stop uncontrolled bleeding in patients with congenital or acquired fibrinogen deficiency following severe blood loss or traumatic injury.

Integrated product development as a guiding principle for our R&D efforts for us also means identifying and optimising the effects and implications of any new development on the entire value chain and for the entire product life cycle. This can only be achieved by including all parties involved, stakeholders and drivers in development processes. We always approach such projects with cross-functional and cross-organisational teams, and sometimes also with external parties, to integrate ideas, requirements and concerns effectively into such projects at an early stage.

We do not only measure our sustainability performance in product innovation – process innovations and continuous improvement are also a priority. This can be seen in Biotest Next Level, the largest investment project in the company's history.

We will be able to achieve significant process improvements, for example, with IgG Next Generation, which not only further increases virus and prion safety, but also further reduces possible side effects such as thromboses or haemolysis.

The new buildings for this project will not only follow Green Building guidelines in order to achieve environmentally friendly construction using low-pollution and low-emission materials. The energy-efficient operation of buildings and facilities is ensured by the use of highly insulated exterior components for the façade, triple glazing, special high-level insulating materials and energy-efficient building technology, so that we will far exceed the energy requirements of the legislator. Additional large investments at the Dreieich site have also given us the opportunity to critically examine and redesign many processes. And so, for example, with the new deep-freeze warehouse, we have also succeeded in converting the plasma incoming logistics so that from now on 150 truck delivery journeys can be dispensed with and this alone reduces our CO<sub>2</sub> footprint by 15 tonnes per annum.

To ensure the products are as safe as possible, we must also fulfil official requirements regarding obligatory animal testing. However, we are currently carrying out a research project aiming to make these tests obsolete if possible using in-vitro testing. We are currently intensively investigating the extent to which studies in patients with acquired fibrinogen deficiency can be reduced by using mathematical models, algorithms and artificial intelligence more efficiently when evaluating scientific literature and other data sets.

Approximately 40 projects are currently underway with universities and treating physicians as part of a more customer-focussed research programme with the aim of developing even more customised preparations for patients and further optimising the best possible benefits for existing products.

The Delegated Regulation 2016/161 came into force on 9 February 2019 as a supplement to the Anti-Counterfeiting Directive. The implementation of these requirements not only requires additional counterfeit-proof security features and unique serial numbers on medications packaging.

An 'end-to-end' verification system and a 'repository system' must also be implemented for continuous data storage along the entire supply chain. Biotest has ensured that the more complex administration of the supply chain can be carried out by investing a considerable amount in IT.

Biotest is guaranteeing better patient safety by going far beyond the legal anti-counterfeiting requirements. A subsequent manipulation attempt now not only causes the seal to be destroyed. For Biotest products, the packaging is also destroyed and thus rendered unusable. Biotest is also in the process of ensuring anti-counterfeiting measures are in place in countries where these legal requirements do not exist. This has already been implemented in China, Saudi Arabia and Oman, countries in which there are usually high counterfeiting rates.

In 2020, countries such as Russia, Brazil and Turkey will follow, showing how important it is for Biotest to effectively anchor safety and sustainability aspects in its supply chains everywhere, even where this is not a regulatory requirement for that.

### **EFFAS E13-01**

#### **Improvement of product energy efficiency compared with the previous year:**

Energy consumption in KWh per litre of processed plasma including Biotest Next Level measured 73.2 KWh/l in 2019, compared with 69.4 KWh/l in 2018.

The reason for this further increase is not higher specific energy consumption or lower energy efficiency in production. The higher consumption is mainly due to the test run for the production launch of Biotest Next Level, which is included in the total consumption. If these effects had not been taken into account, the energy consumption per litre of processed plasma would have been 45.15 KWh/l (46.26 KWh/l in the previous year). This value will continue to drop after commissioning the new facilities, firstly due to the elimination of the extraordinary effects, as well as to the many investments that will result in significant reduction of energy consumption in operations, as described above.

### **EFFAS V04-12**

#### **R&D expenditures**

Research and development expenditure in the financial year 2019 amounted to 12.8% of turnover. Biotest is therefore in the top group of the plasma industry.

No meaningful breakdown into individual, specific sustainability aspects is possible. In the sense that our research and development activities are primarily dedicated to the efficacy, safety, dosing and tolerability of active agents and medications, the major part of our expenditures here can be considered to be related to sustainability.

## **Environment**

### **Use of natural resources**

11. The company describes to what extent natural resources are utilised for its business activity. This includes materials as well as input and output of water, soil, waste, energy, acreage, biodiversity and emissions for the life cycle of products and services.

Our environmental concept is characterised by the fact that we try to minimise the use of natural resources wherever possible, as long as there is no impairment of our central objective, 'maximum product and process safety'.

The main resources used are electricity, natural gas, fuel oil, diesel, gasoline, drinking water, liquid nitrogen, refrigerant and special gases. They are consumed in manufacturing as well as by refrigeration and air conditioning systems, heating and lighting, steam and compressed air systems, water treatment and by the vehicle fleet.

Primary resource consumption was natural gas with 81,665 MWh, electricity at 28,958 MWh (our own power generation amounted to 5,954 MWh), liquid nitrogen at 351 tonnes, 30,173 litres of fuel oil and 54,212 litres of fuel.

Drinking water consumption in 2019 registered 404,432 cubic metres. Wastewater from production is treated in a proprietary facility before being released to the public network.

Waste volumes in production are in direct relationship to the volumes of plasma processed, with the largest portion comprising organic solvents (waste alcohols). These are required for fractionation of the plasma respective its separation and purification. 89% of the total waste volume of 9,483 tonnes was recycled or harvested for reuse. The remaining just over 11% was mainly used for thermal production. To ensure professional waste management, Biotest has commissioned several specialised waste disposal service providers, which are audited by Biotest on a case-by-case basis. In addition to this, Biotest also participates in the dual system for recycling sales packagings.

In 2018, the separation rate of 90% required by the 2017 amendment to the Commercial Waste Ordinance was achieved and certified. We are assuming that the checks for 2019 carried out in March 2020 will show a similar result.

### Resource management

12. [The company describes the qualitative and quantitative goals it has defined for its resource efficiency, use of renewable energies, increased raw material productivity and reduced use of ecosystem services, and how these have been met or will be met in the future.](#)

Our corporate responsibility goes beyond the greatest possible product safety and patient protection. We also strive to minimise the impacts of our business on people and the environment in procurement, development, manufacturing and sales. This includes protecting resources and minimising emissions and waste. Because chemical syntheses are not used in the development and manufacturing of our products, the risk of environmental damage is low. Biotest has nonetheless defined environmental, health and safety guidelines with mandatory resource and environmental protection components.

Blood plasma is the most important resource used for our medications. Resource protection for us means protecting plasma donors as well as their donated plasma. Careful handling of these voluntary donations is a particular obligation for us. One focus of our research and development activities is to utilise donated plasma as effectively as possible on behalf of the donors, by continuously improving efficacy and yield.

The Biotest Next Level project is of key importance in this respect — not only because the production capacity will more than double. Biotest Next Level will also represent a quantum leap in our sustainability performance. Numerous process innovations, specific investments in special insulations, and the use of natural refrigerants such as carbon dioxide will allow us to significantly reduce resource and energy consumption in production per litre of final product, and undercut the German energy savings regulations requirements by 20%.

We will also be able to produce five products from the same volume of raw material that has resulted in three products until now. Biotest will have its new production sites certified by the US Food and Drug Administration (FDA) so that products for the US market can be centrally manufactured in Dreieich, which further improves our production site's resource and energy efficiency. The FDA certification criteria also partially exceed the already strict European requirements and standards, which further benefits product safety and patients.

There are no appreciable social or ecological impacts from the collection, production, sale or use of our products. We produce medications based on natural biological products. Our comparably high energy consumption is only related to freezing and storage as well as the minimum storage and quarantine periods, which commensurately increase product safety and availability.

Biotest has an energy management system certified to DIN EN ISO 50001 and also has two full-time energy managers. They not only have the task of monitoring energy and resource consumption, but also initiating and implementing relevant measures independently with the responsible departments. In recent years, the focus of such measures has been on the installation of more energy-efficient air conditioning systems and pumps, energy-efficient renovation of roofs and windows, and the replacement of conventional light sources with LEDs. A monthly report is made to the responsible member of the Board of Management.

By the end of 2020, we plan to have reduced specific energy consumption by 2.5% compared to 2017, but in view of the many one time effects associated with the completion and commissioning of Biotest Next Level, it is not possible to reliably determine whether the targets have been achieved. However, with the commissioning of Biotest Next Level, we expect a significant reduction in specific resource and energy consumption, and once production has reached a steady state, a reformulation of savings targets is planned.

With regard to the energy mix, the consumption share of renewable energies is to increase further. In 2019, green electricity already accounted for just under 57% through the purchase of certificates.

**EFFAS E04-01 performance indicator:**  
**Total weight of waste**

The total weight of waste at the production site in Dreieich in 2019 was 9,483 tonnes.



**EFFAS E05-01 performance indicator:  
Share of total waste that is recycled**

In 2019, the share of recycled waste including utilised material measured 88.9%.

**EFFAS E06-01 performance indicator:  
Total energy consumption**

Energy consumption for the most important energy sources, which are natural gas, electricity and fuel oil, without the expansion project Biotest Next Level, measured 68,906 MWh in 2019. All properties including Biotest Next Level had an energy consumption of 111,870 MWh in 2019.

**Climate relevant emissions**

13. The company describes its greenhouse gas (GHG) emissions pursuant with the Greenhouse Gas (GHG) Protocol or standards based on this protocol, and shares its self-defined targets for emissions reduction.

Biotest's CO<sub>2</sub> footprint is around 27,807 tonnes (scope 1 and 2 of GHG protocol). The additional 2.5% reduction in specific energy consumption will be accompanied by a reduction in emissions, especially as the share of renewable energies for electricity is to continue to rise as planned. After production start of Biotest Next Level we will decide to what extent this footprint can reasonably be related to other KPI like CO<sub>2</sub> per employee or per litre of processed plasma.

Biotest has not yet been using regenerative energies, which it has produced itself. Alternatively, at Biotest Next Level, we decided to operate a cogeneration plant with combined heat and power. Climate-friendly building air conditioning is achieved through the use of absorption refrigeration systems, which, according to the German Federal Environmental Agency, represent an economically and ecologically sustainable solution.

For the main energy sources electricity and gas, the above-mentioned specific reduction targets are quantified. For the other energy sources, we also aim to reduce their consumption without setting any targets. There are currently numerous relevant projects in this context, ranging from the replacement of lighting fixtures in production facilities with LEDs, the replacement of inefficient air conditioning systems, to comprehensive building measures such as roof refurbishment and special insulation.

The freezing of blood plasma is a critical process for its safety, shelf life and storage. With effect from 1 January 2020, the use of the refrigerant R404A in new systems is no longer permitted and is regulated in existing systems. Against this background, Biotest took measures at an early stage by converting to CO<sub>2</sub>, combining or decommissioning old plants in order to be able to completely dispense with R404A in the future. The investment made in 2019 for the replacement of refrigeration systems and refrigerants amounted to approx. 1.5 million euros,



enabling refrigerants with a high GW potential or a CO<sub>2</sub> equivalent of 240 tonnes to be replaced by climate-neutral refrigerants. In 2020 another 6 cold storage cells shall be converted.

In 2019, we were able to save 50.6 tonnes of CO<sub>2</sub> emissions by raising the awareness of our employees to the emission effect of the chosen means of transport on business trips - for example, by using rail instead of cars. We are equally committed to expanding our electro mobility, e.g., through the conversion of the plant security vehicles accordingly and the installation of a total of 10 electric charging stations in the parking garage for our employees.

**EFFAS E02-01 performance indicator:**

**Total GHG relevant emissions**

<b>2019 including BNL</b>			
<b>GHG-relevant emissions</b>	<b>Amount</b>	<b>CO<sub>2</sub> equivalents</b>	
Electricity	28.957.570 kWh	8,455.6	t CO <sub>2</sub>
Fuel oil	30.173 l	95.7	t CO <sub>2</sub>
Natural gas	81.665.394 kWh	17,966.4	t CO <sub>2</sub>
Diesel	53.711 l	156.3	t CO <sub>2</sub>
Gasoline	501 l	1.4	t CO <sub>2</sub>
Refrigerant	704 kg	1,131.8	t CO <sub>2</sub>
	<b>Total</b>	<b>27,807.2</b>	<b>t CO<sub>2</sub></b>

Compared to the previous year, our CO<sub>2</sub> emissions are around 16% (5,141 tonnes) lower. This is not only the result of less electricity consumption but also of Biotest considering more carefully its mix of electricity sources with a higher proportion of renewable energies than the standard values of the German Federal Environment Agency, which bases its values on the German averages and was the basis for calculations in previous years.

**Company**

**Employee rights**

- 14. The company reports on how it meets nationally and internationally recognised employee rights standards, and promotes the participation of employees in the company's sustainability management.

The vast majority of Biotest employees in 2019 were employed in European Union member states. UN human rights standards and ILO (International Labour Organisation) basic labour standards are already anchored in the law in these countries. The four basic principles of the

ILO are freedom of association and collective bargaining, the elimination of forced labour, the abolition of child labour and the prohibition of discrimination in employment and occupation. Biotest naturally implements these standards.

In Germany, the participation rights for employees and employee representatives are stipulated in the Works Council Constitution Act, which ensures extensive information and participation rights (e.g. works council members released from their work duties; representation of employees in the Supervisory Board). Regular constructive dialogue with employee representatives takes place for all topics that pertain to these rights. This ensures a balanced consensus on major issues within the company, for this we do not assume relevant risks regarding employee matters or pursue further respective goals.

Fair treatment and a partnership relationship with employees is for us the foundation and prerequisite for long-term business success. Biotest therefore wants to provide employees with a work environment where they are happy to work and able to develop. Employees are surveyed at regular intervals, so as to better understand their expectations and apply these to company policy in a structured manner.

A variable remuneration system with target agreements as a management tool is implemented that supports overall company goals of efficient use of resources and profitability.

As already explained, our business model and core products are sustainable, and sustainability constitutes an integral part of our corporate DNA. Therefore we actually do not consider sustainability management as an isolated or separate initiative which we have to encourage staff to embrace separately. Nevertheless, in 2019 we launched a new initiative in the field of climate protection for and with our trainees: we have declared them 'energy scouts'. This is linked to the task of identifying and evaluating potential opportunities to save energy and CO<sub>2</sub> throughout the company in order to then evaluate measures as well as their cost-effectiveness and implementation.

Of course, we also support initiatives such as the project 'Climate Savers – Lifesavers' (also see criterion 5), and even the top management has got involved with this.

### Equal opportunity

15. The company describes how it implements national and international processes and its goals in the area of promoting equal opportunity and diversity, occupational safety and health, integration of migrants and people with disabilities, reasonable remuneration and work-life balance.

## **Equal opportunity**

As an employer we tolerate no discrimination for reasons of gender or sexual orientation, religion or ideology, ethnic origin, nationality, disability or age. This is laid out in Biotest's mandatory Code of Ethics and Business Conduct. We value our employees and their contribution to the company's success. We promote equal opportunity. Biotest fills open positions based on skill, performance and potential, and job adverts are written gender neutral. We keep management continuously informed of legal requirements.

It is also part of our identity to treat our business partners in the same manner.

We protect the rights of our employees and prevent any form of discrimination. No violations against the discrimination ban were observed in 2019.

## **Diversity management**

Diversity in the workplace and a workplace culture of acceptance and appreciation are of key importance to our worldwide success. Our employees come from many different countries, cultures and generations. This is also reflected in the wide variety of individual abilities, experiences, attitudes, values and ways of thinking within the company. And we are working to further increase that diversity.

## **Equal pay for men and women**

An important aspect of our corporate culture is to recognise the individual performances of our employees, including with appropriate remuneration in line with the market. We do not differentiate between genders, so there are no systematic differences between the remuneration of our female and male employees. Beyond remuneration structures, we are particularly interested in expanding the share of women in management positions.

## **Health management and occupational safety**

The health of our employees is their most precious resource, and protecting it is therefore our ultimate obligation. This not only applies to the working environment of our employees, but also to their private lives. Our long-term goal is "zero accidents". We therefore work constantly to further improve occupational safety. With 7 (2019) and 10 (2018) recorded occupational accidents (5.4 per thousand full time employees in 2019), Biotest is once again well below the average of companies covered by BG RCI, which is still more than 18 accidents per thousand full-time employees.

Occupational safety and health are documented in binding company agreements. These reference among other things training and education around occupational safety and difficult work conditions, on-call service, work hours, addiction assistance, improvements in

occupational safety, protection of non-smokers, integration agreements and occupational integration management as well as provision of work clothing and subsidies for medications, therapies and medical devices.

A company health management service actively promotes the health and well-being of our employees. Lessons and training in the area of health are an everyday occurrence, as is the regular Biotest Health Day covering different topics each year, such as vital screenings, mobility checks, relaxation techniques at work and the opportunity to rent an e-bike. First aid training courses, trainings around accident prevention regulations and workstation assessments by the occupational medicine service are regularly offered.

### **Work-life balance**

Work-life balance is not merely a recent social issue for us. We are aware that we can only benefit from and maintain the abilities and talents of our employees if we as an employer strongly support their ability to manage the challenges of balancing their professional and personal lives.

As a family-friendly company, we therefore not only foster flexible work relationships that allow our employees to find a good balance between their jobs, families and free time. Our company childcare centre BioNest, which opened in 2015 with 1,400 sq. m for up to 80 children, was judged by the Mayor of the town of Dreieich to be the nicest childcare in the area. Small groups ensure that the carers are able to meet the children's individual needs. Our employees value the diverse activities offered their children, and the fact that the childcare is only closed between Christmas and New Year's. Its hours of operation from 6 AM to 6 PM on work days is our way of contributing to the work-life balance of our employees with small children.

We are conscious of the importance of flexible work options to increase performance, motivation and productivity. This not only includes our offer of numerous, individually tailored part-time work, flexible work hours and self-managed flexitime models for employees not covered by collective bargaining agreements. We are also currently exploring the possibilities of an even more autonomous and trust-based workplace philosophy, where performance outweighs presence, to further contribute to personal flexibility for our employees.

### Qualification

16. The company describes the goals it has set and the measures taken to promote the employability of all employees, i.e. their ability to participate in the workplace and professional sphere, and adapt to demographic developments.

Our success is determined by the motivation, knowledge and abilities of our employees. Continuous development and lifelong learning for our employees is therefore a key component of our human resources policy.

To support employee loyalty and retention and their profitable contribution to the development of the company, our HR department uses an integrated approach. It begins with recruiting apprentices, supporting and promoting students, and extends through trainee programmes and support for new graduates in entry-level positions, to human resources development for specialists and management. We highly value the professional and personal development of our employees, not least through an international management programme for cross-functional and international training in leadership and management skills for potential candidates.

Particularly with respect to demographic developments, an ageing workforce and significantly rising age of retirement, the lifelong learning aspect and company health protection play an important role in promoting health and employability and preventing disease.

Offers to support employees in caring for their families are also gaining importance. Not only is the workforce getting steadily older, the share of people in need of care is also rising. More and more employees must care for ageing family members, in addition to their work responsibilities. Biotest therefore supports its employees with various instruments to assist with such family care responsibilities (for example flexible working hours).

We assume that the average age of our workers will continue to rise as a result of demographic evolutions. We also assume that highly qualified workers will continue to become scarcer in the external labour markets. Measures to further increase Biotest's attractiveness as an existing and potential employer are therefore key to employee retention and attraction.

This includes adapting jobs to the needs of ageing individuals and expanding health management to sustain health and performance. From regular health awareness days with varying special topics such as, in 2019, autogenic training in sitting, chair yoga, healthy movement and ergonomics with practical exercises and options for standing desks for employees with primarily seated tasks — Biotest has implemented numerous initiatives to better protect its employees' health and meet the changing requirements and consequences of demographic change. Health protection is not just physical, but also has a psychological dimension. Here, we also like to adopt unconventional ways, such as happiness workshops that run over several weeks, or resilience training, which we offered as part of the Biotest Impulse Days 2019

We address the foreseeable increased scarcity of highly qualified employees above all with measures to further increase our attractiveness as a current and future employer. We include here, in addition to initiatives already described, a parking garage with free parking for our employees. In addition Biotest offers an above-average pension packages and proprietary. Strong collaboration with universities, targeted support for Bachelor and Master courses, sponsorships in the graduate environment and participation in job fairs also contribute significantly to our positioning as an attractive future employer. And last but not least, Biotest supports the Frankfurt Goethe University and its best students with the German scholarship –

in 2019, 500 talented and committed students were awarded a grant of 3,600 euros in addition to a non-material support program, to allow them to focus on their studies.

#### [EFFAS S03-01 performance indicator](#)

#### **Age structure and distribution / number of full-time equivalents (FTE) per age group in the company**

With regard to the indicators age structure as well as the proportion of women in the total workforce and in management positions, we report by head count and not by full-time equivalent because they are more meaningful. At the end of 2019, our more than 1,943 employees belonged to the following age categories:

Age group	Number of employees	Share in %
<30 yrs	343	18%
30-39 yrs	550	28%
40-49 yrs	482	25%
50-59 yrs	453	23%
>= 60 yrs	115	6%
<b>Total</b>	<b>1,943</b>	<b>100%</b>

#### [EFFAS S10-01 performance indicator](#)

#### **Share of female FTE in the company's total workforce**

The share of female employees in the total workforce as at 31 December 2019 was 53%.

#### [EFFAS S10-02 performance indicator](#)

#### **Share of female FTE in management positions compared with total FTE in management positions**

Biotest has divided management into two groups, executive management and top management. In executive management, the share of women is 12.5%, and in top management, this figure is 28%. Women constituted 50% of the Supervisory Board in 2019.

#### [EFFAS S02- 02 performance indicator](#)

#### **Average expenditures for training per FTE per year within the company**

The total costs for training in 2019 were €562 on average per employee (FTE).



## Human rights

17. The company describes the measures taken for the supply chain to ensure that human rights are respected worldwide and to prevent compulsory and child labour as well as any manner of exploitation.

Biotest is unreservedly committed to respecting and supporting human rights. As a company with headquarters in Germany, we are subject not only to all national standards, but also to the guidelines of the Organisation for Economic Cooperation and Development (OECD) for multinational companies. Compliance with the United Nations Guiding Principles on Business and Human Rights and the International Labour Organisation's basic labour standards is also compulsory. Due to our headquarters and production being located in Dreieich, only a few small foreign sales subsidiaries and a highly regulated and transparent value chain, we can rule out human rights infringements and compulsory and/or child labour in the Biotest Group. Hence we do neither apply specific concepts nor we see risks regarding these issues.

However, our corporate responsibility does not stop at our internal processes or at the boundaries of our plants, but rather encompasses the entire pathway from donor to patient. We can exclude any child, compulsory or forced labour in the areas of the value chain that are under our responsibility and influence. Our suppliers are almost exclusively in industrialised Western countries, and are subject to similar protective laws and regulations, so that here as well there are no opportunities for unethical employment practices. We also try to procure as much as possible from local and regional sources. Where this is possible and reasonable, we bundle our needs with large, capable suppliers, whom we know not least thanks to our supplier audits that they comply with human rights and labour standards.

For construction works or procurement of capital goods where a supplier works with subcontractors, who may not be subject to such strict standards, our standard contracts contain assurances that social insurance contributions are made, a minimum payment level is met and employees come from the EU and/or have valid work permits. Each contractor is obliged contractually to ensure that these assurances are complied with and any subcontractors are similarly obliged contractually.

### EFFAS S07-02 II performance indicator **Percentage of all facilities that are SA8000 certified**

SA8000 is an international standard aimed at improving the working conditions of employees (employees, workers, but also temporary workers). Launched by Social Accountability International (SAI), an international non-governmental organization based in New York, USA, it primarily serves transnational companies as a minimum requirement for social and labour standards. In a context where Biotest has production sites only in Germany, and the standards



that apply there exceed the requirements of SA8000 or are integrated into the relevant laws, we do not seek separate certification in this area.

## Community

### 18. The company describes how it contributes to the community in the regions in which it has significant business operations.

Biotest sees itself not just as an employer, but as a member of society, in Dreieich and at its international locations. We not only create jobs in these regions, we also invest in the qualifications, social security and future prospects of our employees. We create prospects for young people on the job market not only by permanently increasing the number of traineeship positions. We have also exploited the size and technical complexity of Biotest Next Level to the point where we can henceforth train mechatronics engineers and warehouse logistics personnel.

Many companies in the vicinity supply us with goods and services. We are the largest employer, one of the largest business tax payers in Dreieich, which makes a significant contribution to the municipal budget and to the community. By making a donation to the Dreieich fire brigade, we have helped to improve health and safety with special vehicles ensuring that the emergency services are now exposed to potential pollutants for as little or no time as possible.

In 2019, we joined the FrankfurtRheinMain ecoprofit initiative not only to obtain further impetus for climate protection measures from local authorities and companies based here. We also wanted to make our own contributions to best practice exchanges to show that the combined savings of this round in 2018 of over 1,000 tonnes of CO<sub>2</sub> can be further increased.

Together with the founding family Schleussner, we sponsor the Paul Ehrlich and Ludwig Darmstaedter award for pioneering research in medical science with substantial sums. This prize is awarded to researchers in Germany and abroad with outstanding achievements in the areas of medicine that Paul Ehrlich worked in. Numerous award winners have subsequently been awarded a Nobel Prize. We also sponsor the Rudolf Pichlmayr award for outstanding performance in the field of transplant medicine and, in 2019, we inaugurated the Georg Kreymann-doctoral award for emerging scientists in intensive-care medicine.

We also support public interest initiatives, often in collaboration with our employees.

Our social engagement is primarily directed towards issues that are closely related to our business and/or our problem-solving capabilities. We therefore work to support people with critically and chronic diseases, projects in healthcare and environmental protection, and cultural initiatives and educational projects. New is our support of the "Care for Rare" foundation, which is trying to raise awareness for children with rare diseases and who lack therapy options by attracting attention to them as "orphans of medicine".

A severe chronic disease influences the life of a patient not only physically, but often also has significant psychological and social consequences for the patient and their family. It is therefore important for people to have support from others in overcoming their problems, and to be able to connect with other people in similar situations. Patient organisations make valuable contributions in this area. Patient organisations make valuable contributions in this area, and therefore receive financial support from Biotest, in some cases for 40 years. Beneficiaries include the German Haemophilia Society Against Bleeding Diseases (DHG), the World Federation of Hemophilia (WFH), the International Patient Organization for Primary Immunodeficiencies (IPOP), the Jeffrey Modell Foundation (JMF), the German Hereditary Immunodeficiency Self-Help Organisation (dsai) and the European Haemophilia Consortium (EHC).

We also serve in places where healthcare systems do not yet support adequate care for the seriously ill. This is why Biotest is also a partner to the World Federation of Hemophilia's 'Recovery' project, currently suspended for regulatory reasons, which supplies patients in developing countries with lifesaving medications free of charge.

Healthy people can laugh themselves sick – and sick people well. That is why we support Dr Eckart von Hirschhausen's "Humor hilft heilen" ("humour helps heal") foundation for patients young and old. The foundation's professional clinic clowns bring amusement and fun into the hospital, help forget worries and offer hope and courage – for patients who may find little to laugh about due to their illness, treatment or specific situation.

With the promotion of SC Hessen Dreieich to the Southwest Regional League, the safety requirements of the DFB [German Football Association] also increased in 2018. The fans of the home and visiting teams have to be separated not only in the stadium, but also outside as well as on their way there. Biotest is happy to continue to provide the parking garage free of charge for guest trailers, despite the recent relegation.

A Biotest team participated in the Dreieicher Stadtradeln cycling initiative as a sign for the increased use of the bicycle in municipalities and were awarded a special mention. Having cycled over 21,000 kilometres and with a saving of around 3 tonnes of CO<sub>2</sub>, our employees not only covered the most kilometres, but also took first place and received the gold award for this from the Climate Alliance and the city of Dreieich.

We do not follow a separate concept with regard to the community, not least because there are no significant risks associated with our business activities here.

## Political advocacy

19. All significant input to the legislative process, all memberships in lobby lists, all significant payments of membership contributions, all contributions to governments and all donations to parties and politicians should be presented, differentiated by country.

Biotest has adopted a comprehensive Code of Ethics and Business Conduct, which governs the position and behaviour of the company and its employees with respect to stakeholders. Conduct with parties and influence on political processes and legislation is clearly defined here: We do not involve ourselves in current politics, and we support no political parties.

To the extent that concerns of Biotest are impacted by health and financial policy, we comply strictly with legal requirements when conducting all necessary lobbying efforts. We also respect and support the right of employees to take part in politics as private individuals and to engage in the political activities of their choice, as long as this is clearly understood to be a personal activity that is entirely independent of any employment with Biotest.

Therefore, no donations or contributions to political parties or similar contributions to others were made in 2019.

Biotest is a member of the following associations and organisations:

PPTA (Global/ Europe).....	<a href="http://www.pptaglobal.org">http://www.pptaglobal.org</a>
EUCOPE.....	<a href="http://www.eucope.org/en">http://www.eucope.org/en</a>
BPI (& BPI Hessen).....	<a href="http://www.bpi.de">http://www.bpi.de</a>
PPTA Deutschland.....	<a href="http://www.pptadeutschland.org">http://www.pptadeutschland.org</a>
AKG.....	<a href="http://www.ak-gesundheitswesen.de">http://www.ak-gesundheitswesen.de</a>
GHP German Healthcare Partnership.....	<a href="http://www.germanhealthcare-partnership.de">http://www.germanhealthcare-partnership.de</a>
VCI.....	<a href="https://www.vci.de">https://www.vci.de</a>
VCI Hessen.....	<a href="https://www.vci.de/hessen">https://www.vci.de/hessen</a>
HessenChemie.....	<a href="https://www.hessenchemie.de">https://www.hessenchemie.de</a>
DIN e.V.....	<a href="https://www.din.de">https://www.din.de</a>
DICO e.V.....	<a href="https://www.dico-ev.de/">https://www.dico-ev.de/</a>
Stifterverband dt. Wissenschaft.....	<a href="https://www.stifterverband.org/">https://www.stifterverband.org/</a>

On 16 August 2019, the German law for more safety in the supply of pharmaceuticals (GSAV) came into force. Among other things, it includes major new regulations for the field of haemophilia. For example, the distribution channel for haemophilia drugs prescribed in the German Medicines Act will be changed, with a transitional period until 15 August 2020; due to the change in the law, the preparations will no longer be distributed to patients by the attending physician, but by the pharmacy. Biotest is adapting its marketing and logistics to these changes.

In its 19<sup>th</sup> legislative period, the German Government plans to launch a cross-departmental agenda 'from biology to innovation' together with industry, science and civil society. The aim here is to strengthen the innovative power of Germany as a business location by improving framework conditions. Biotest would be positively affected by the measures currently under discussion, such as reducing bureaucracy in approval processes, improving technology transfer, R&D support programmes and better funding opportunities for R&D projects.

The same applies to the national bio-economy strategy, which the government intends to use to shape research funding and political framework conditions. Unfortunately, Biotest does not benefit from the Research Subsidies Act passed in November 2019 because the German government has set the assessment basis considerably lower than other European countries.

In addition, Biotest has been affected by several of the 221 legislative initiatives submitted to the Bundestag in 2019, such as the Second Shareholder Rights Directive (ARUG II), which came into effect on 01 January 2020, the law on the protection of trade secrets (GeschGehG) and changes in social and labour legislation. Against the background that these, however, only have a small impact on the business model, cost structure or sustainability management, a further presentation is dispensed with here, especially since these laws apply to many or even the majority of companies operating in Germany.

#### **EFFAS G01-01 performance indicator**

#### **Payments to political parties as a percentage of total revenue.**

0 (Zero €)

### **Corruption**

20. The company describes the measures, standards, systems and processes that are in place to prevent illegal conduct and in particular corruption, and how they are verified. It describes how corruption and other breaches of the law are prevented, identified and sanctioned in the company.

Just as Biotest strives for the highest level of safety in the manufacture of its products, our business conduct is also subject to the highest ethical standards. These are defined in the Code of Ethics and Business Conduct, and apply without exception to all employees including the

Board of Management. A full-time risk and compliance officer has been appointed who reports directly to the Board of Management and is represented in important decision-making bodies of the company. His duties include the regular assessment of the efficiency of overall compliance management. Any deviations from our obligatory compliance standards are therefore monitored consistently.

As an international company, we are subject to very different expectations and customs in our markets (e.g. expectation of bribes, “speed money” or other favours). We address the resulting risks by means of compliance measures adapted to the risk profile of our foreign business partner with a particular focus on sales representatives and distributors. Before entering into a business relationship, we not only require these to give written consent to the principles of our Code of Ethics and Business Conduct and the disclosure of beneficial owners, reference customers and past compliance violations as part of a due diligence questionnaire. We also check all sales partners abroad for suspicions of corruption, money laundering or other crimes or unethical behaviour against social and environmental standards when the contract is concluded and periodically thereafter on the basis of a risk-based approach.

For doubts not resolved and for business partners from high-risk countries (according to the Transparency International Corruption Perceptions Index), we further examine this information in detail in fee-based databases or commission external specialist service providers to conduct an in-depth review of this information. Biotest also reserves the right to terminate contracts with external partners in the case of compliance deviations.

In close cooperation between the compliance, legal and IT departments, the international compliance system was further expanded and adapted to current requirements, taking into account the country specific aspects. The compliance processes were further developed in 2019, primarily by designing an electronic compliance review process, establishing processes to prevent money laundering and database-supported reviewing of business partner compliance.

In the compliance manual for Germany, Biotest has integrated the code of conduct of the AKG (medication and health system cooperation organisation) on requirements in dealing with so-called health care professionals (physicians, pharmacists and nurses) as the local guideline. International Biotest group companies have their own, customised compliance manuals based on the requirements of each national pharmaceutical industry association.

Our compliance programme has four key elements:

1. mandatory training on the Biotest Code of Business Conduct for all new employees and in case of major changes to the Code for all employees, as well as annual specialist training on the compliance manual for affected functional areas
2. support from the central Compliance department and local compliance officers

3. monitoring, checking and investigation - Biotest continuously monitors all invoices of members of health care professionals from a compliance point of view; in addition the headquarters Internal Audit regularly reviews business activities in terms of compliance with laws and relevant guidelines
4. internal and external telephone hotline to a law firm to report possible breaches, anonymously if desired.

Infractions of the compliance regulations result in legal employment measures up to and including termination. This reporting year there were no such infractions. Disciplinary measures may also be taken against management, if misconduct by employees is ignored or not corrected. Since executives play a special role also in compliance issues with regard to role models and responsibilities, a separate section is devoted to them in the Code of Ethics and Business Conduct. There it is bindingly documented in 10 points which special expectations are placed on these and their behaviour.

For cases of corruption and any costs associated with these, see EFFAS V01-01.

#### [EFFAS V01-01 performance indicator](#)

#### **Expenditures and penalties resulting from litigation and court proceedings for anti-competitive conduct, cartel and monopoly infractions**

Three employees of Biotest Italia Srl., an Italian subsidiary of Biotest AG, are suspected by the Naples public prosecutor's office of involvement in illegal pricing agreements for tender business in the Naples region. The proceedings are still ongoing, the subsidiary is not the subject of the investigations.

The expenses for these cases amounted in 2019 to € 45,087.

#### [EFFAS V02-01 performance indicator](#)

#### **Percentage of revenue in regions with a Transparency International Corruption Index below 60.**

We manufacture biological medications, with which we ensure the survival of people with severe diseases and the quality of life of people with chronic diseases. Even when these patients live in countries where corruption is at concerning levels, what is at stake is fellow humans who are sick, and to a large degree they depend on our support and our products – no matter the corruption rating of the country they live in.

In applying our sustainability promise to “take responsibility”, we do not differentiate people who need our help to survive by the country in which they reside. Moreover, in our opinion, being guided exclusively by the Transparency Index leads to an ethically unacceptable form of economic embargo against people from poor countries that regularly come very low on the

Index. We therefore regard using the Transparency Index as the sole criterion when determining whether or not to do business in a given country as problematic.

However, we pay particular attention to ensure that all activities in high-risk countries are fully compliant with the Biotest compliance guidelines by increased scrutiny of compliance risks with business partners from these countries both before and during our business relationship.

The share of total revenue generated from continuing operations in regions with an index value below 60 was 45.5% in 2019.

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