

Anton Debatin GmbH, Vichystr. 6, 76646 Bruchsal

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DENMARK

Bruchsal, 25.07.2022

Dear Sir or Madam,

Our sustainable product and corporate strategy are an essential part of our philosophy: we must assume responsibility and play our part in improving the environmental situation.

We work tirelessly to minimise the resources we use and make our manufacturing processes more efficient and climate-friendly:

- Our company and **our products are climate-neutral** (Cradle-to-Gate). We compensate for any unavoidable CO2 emissions via carbon offsetting.
- In 2010/2011 we began to focus on **using and processing sustainable and renewable materials**.
- Together with our partner companies in the DERIBA Group, we're working to **reduce our overall use of materials** in order to protect the environment.
- We're committed to **recycling management** and have implemented our own **recycling and material loop** (DERIBA Cycle) within our company group (DERIBA Group). For example, we recycle used film material to recover new PE raw materials and thus **save valuable resources**.
- Besides continuously improving our products, we also focus on our energy efficiency. This area is monitored and improved by an environmental management system, enabling us to permanently reduce our energy consumption and our CO2 emissions.

In addition, we face the increasingly growing demands on product safety and deal intensively with compliance with various EU directives and regulations.

All our products and the materials supplied to us according to the manufacturer's certificate are in full compliance with the guidelines / regulations and recommendations listed below:

- Montreal Protocol
- Denmark Order No. 1082 (1012 was terminated)
- Norway: MVD Regulation 1544
- FDA 21 CFR 177.1520 olefin polymers
- FDA 21 CFR 175.105 adhesives
- BfR recommendation III - polyethylen
- BfR recommendation VII - polypropylen
- GHS - Verordnung (EG) Nr. 1272/2008 (CLP)
- EU Guideline 2018/852 for changing of EU Guideline 94/62/EG concerning packaging and packaging waste
- EU Guideline 2015/863 the list of restricted substances
- EU Guideline 2019/1021 persistent organic pollutants.



The products:

DEBABAG	-	flat bags
DEBAGRIP	-	resealable grip bags

are also in full compliance with the following listed regulations and guidelines:

- ★ **EU Directive 10/2011 concerning materials and plastic objects which are intended to come into contact with foodstuffs** - in their current version
- ★ **LFGB German Food and Feed Code**
- ★ **Guideline (EG) Nr. 1935/2004 concerning materials which are intended to come into contact with foodstuffs**
- ★ Directive (EG) 2023/2006 on good manufacturing practice for concerning materials and plastic objects, which are intended to come into contact with foodstuffs.

The products:

DEBAMED	-	medical bag
Specibag	-	medical bag
Specigard	-	medical bag

are also in full compliance with the following listed regulations and guidelines:

- ❖ Packing instruction P 650
- ❖ Liquid sealed design

REACH

We confirm, that the products which we deliver to your Company do not contain substances from the candidates list (Update 10.06.2022) confirm article 59 (1) of the regulation (EG) Nr.1907/2006 ("REACH") (<http://echa.europa.eu/de/candidate-list-table>).

We confirm, that restrictions and prohibitions on materials according to Appendix XVII of the REACH-Guideline are observed.

Our target is a fast and uncomplicated communication with our customers regarding the REACH – Regulation. In case of questions please contact:

Name: Veronika Stricker
Position: Quality engineer
E-Mail: veronika.stricker@debatin.de

Others

- Substances referred to in the Chemical Act and being part of the list of banned substances, i.e. heavy metals and azo-dyes, have been entered in the German Regulations for packaging. The limiting values of the materials used in our production fall below the therein indicated maximum permissible values.
- We inform, that the from us used materials, referring to our suppliers formulation don't contain
 - **Dimethyl Fumarate (DMF) respectively radioactive steel**
 - **Cobalt Dichlorid**
 - **Latex**
- Our masking tapes and backing papers are with a percentage of 0,5 – 12% depending the weight of unit area with silicon coated, this is no hazardous substance pursuant to the hazardous substance regulation and according the EG-Guidelines.
- Drying Bags are not used in our packaging!

ANTON DEBATIN GmbH

Confirmation is valid without signature.

Our declaration is based on the data of our previous suppliers. Although the substances which subject to limitations in above mentioned regulations are not used or added on purpose, the presence of negligible hints caused by e.g. contamination can't be excluded fully. As the appearance of those substances is seen as very unlikely, we abandon a chemical investigation to prove their absence due to economical reasons.