## STATEMENT ON COMPLIANCE TO REGULATIONS ON MEDICAL USE

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# Polypropylene
# Bormed™ TD109CF

We confirm that this product fulfils the requirements on materials used for the manufacturing of articles or components of articles intended for medical use as described in:

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|---|---|
| **Council of Europe** | Material complies with the following European Pharmacopoeia monographs:<br>Monograph 3.1.3. Polyolefins<br>Tests are made according to the current Pharmacopoeia edition at the time of the testing: 11th edition (2023), and supplement 11.2 (07/2023). (<br><br>Monograph 3.2.2. Plastic containers and closures for pharmaceutical use: This monograph relates specifically to the container and closure system and does not contain tests that are required for compliance assessment of the raw materials used for said container and closures. The composition of the product is in compliance with this monograph. |
| **Germany** | The product follows the VDI 2017 Guideline on “Medical Grade Plastic” that covers the requirements for change management, quality management, supply security and support for regulatory requirements. |
| **USA** | Material has passed the following United States Pharmacopeia tests:<br>Biological reactivity tests - in vitro <87>: Cytotoxicity (Elution test)<br>Biological reactivity tests - in vivo <88>: Class VI - 70 °C<br>Physicochemical tests for plastics according to <661>, so far applicable to polymer pellets (with no reference to the specific surface area requirements), including heavy metals, buffering capacity and non-volatile residue test with purified water extract.<br>Plastic materials of construction <661.1>: Identification, physicochemical and extractable metals (as listed in the chapter) tests. Plastic additive tests are done according to Borealis’ internal methods.<br>Tests are made according to the current Pharmacopeia edition at the time of the testing (USP 29/42/2022). |
| **Elemental impurities** | During the manufacturing process of this product, we neither use nor intentionally incorporate any Class 1, 2A, 2B or 3 elements as listed in the ICH Q3D(R2) Guideline on Elemental Impurities (May 2022). |
| **DMF number** | Material has been assigned the FDA Drug Master File number(s):<br>DMF 024931 |
| **Additional information** | If a customer wishes to take advantage of the pre-notice period in case of deletion or modification of Bormed grades, such pre-notice period needs to be included in Technical Delivery Specifications.<br><br>This edition of the document supersedes any previous editions.<br>Borealis reserves the right to modify this document at any time, so please ensure to view it frequently. Changes to this document may be made with or without notice. Please always ensure that you are viewing the latest edition by downloading documents directly from our website at www.borealisgroup.com. |
| **Prepared by** | Borealis, Group Product Stewardship |

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