



**Polypropylene**  
**Bormed™ HD810MO**

## STATEMENT ON COMPLIANCE TO REGULATIONS ON MEDICAL USE

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

**Council of Europe** European Pharmacopoeia, 5th edition (2004), and supplement 5.8 (07/2007) Monograph 3.2.2. Plastic containers and closures for pharmaceutical use

**USA** The product has passed the United States Pharmacopeia testing including Class VI tests and has been assigned the FDA Drug Master File No.: DMF 9040.

**Additional information** Material has successfully passed the biological tests according to ISO 10993 - external communicating devices for indirect blood contact for a prolonged period.

**Prepared by** Borealis Group Product Stewardship / Hanneli Seppänen

### Disclaimer

**The product(s) mentioned herein are not intended for use as medical implant material or implantable medical devices and we do not support their use for such applications.**

To the best of our knowledge, the information contained herein is accurate and reliable as of the date of publication, however we do not assume any liability whatsoever for the accuracy and completeness of such information.

**Borealis makes no warranties which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.**

**It is the customer's responsibility to inspect and test our products in order to satisfy itself as to the suitability of the products for the customer's particular purpose. The customer is responsible for the appropriate, safe and legal use, processing and handling of our products.**

No liability can be accepted in respect of the use of Borealis' products in conjunction with other materials. The information contained herein relates exclusively to our products when not used in conjunction with any third party materials.

Bormed is a trademark of Borealis A/S, Denmark.

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