medical systems

# EC DECLARATION OF CONFORMITY

**Manufacturer:** B Medical Systems S.à r.l.
17, op der Hei
L-9809 Hosingen

**Product:** Blood Storage Refrigerators

**Models:** B51, B131, B291, B381, BF261

**GMDN Code:** 35486

**Intended use:** Blood storage refrigerators are devices intended for the safe storage of whole blood and blood components (e.g. blood cells or plasma) at temperatures ranging from 2°C to 6°C. The devices include an integrated alarm system that warns against unexpected temperature excursions and power failures as well as a safety thermostat that protects the products from freezing.

We hereby declare under sole responsibility, that the above listed products are in conformity with the following directives, standards or other referenced normative documents and regulations.

**Directive 93/42/EEC (Medical Devices) amended by 2007/47/EC**

| | |
|---|---|
| Class: | IIa |
| Classification rule: | Rule 2 acc. to the MDD 93/42/EEC, Annex IX – Non-invasive products |
| Assessment: | Annex II (excluding Section 4) |
| Certificate No.: | G1 16 04 95256 002 |
| Validity: | 31.07.2021 |
| Notified body: | TÜV SÜD Product Service GmbH, N° 0123<br>Ridlerstraße, 65<br>D-80339 München |

**Directive 2014/35/EU (Low Voltage)**

| | |
|---|---|
| Applied standards: | EN 61010-1:2010<br>EN 61010-2-011:2017<br><br>IEC 61010-1:2010 (3rd Edition)<br>IEC 61010-2-011:2016 |
| Certificate No.: | 244848-70131339 |
| Report No.: | 244848-70131339 |
| Test Institute: | CSA Group<br>Weismüllerstr. 45<br>D-60314 Frankfurt |

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**Directive 2014/30/EU (EMC)**

Applied standards: EN 61326-1:2012
EN 61326-1:2013

CISPR 11:2009 mod.+A1:2010, CISPR 11:2015 mod.

EN 55011:2009+A1:2010, EN 55011:2016
EN 61000-3-2:2006+A1:2009+A2:2009, EN 61000-3-2:2014
EN 61000-3-3:2008, EN 61000-3-3:2013
EN 61000-4-2:2009
EN 61000-4-3:2006+A1:2008+A2:2010
EN 61000-4-4:2004+A1:2010, EN 61000-4-4:2012
EN 61000-4-5:2006, EN 61000-4-5:2014
EN 61000-4-6:2009, EN 61000-4-6:2014
EN 61000-4-11:2004

IEC 61000-3-2:2005+A1:2008+A2:2009, IEC 61000-3-2:2014
IEC 61000-3-3:2008, IEC 61000-3-3:2013
IEC 61000-4-2:2008
IEC 61000-4-3:2006+A1:2007+A2:2010
IEC 61000-4-4:2004+Cor.06:2007+A1:2010, IEC 61000-4-4:2012
IEC 61000-4-5:2005+Cor.10:2009, IEC 61000-4-5:2014
IEC 61000-4-6:2008, IEC 61000-4-6:2014
IEC 61000-4-11:2004

Report No.: 0004/17, 0039/17, 0040/17, 0041/17, 0042/17, 0043/17, 0045/17, 0046/17, TB0538/17

Test Institute: Steep GmbH
Justus-von-Liebig-Straße 18
D-53121 Bonn

**Regulation (EC) No 1907/2006 (REACH)**

We hereby declare that the products covered in this declaration meet the provisions of the REACH regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals. We declare that none of the substances in the Conditions of restriction is present in our products.

**Directive 2011/65/EU and 2015/863 (RoHS)**

We hereby declare that the products covered in this declaration are compliant with all provisions and exemptions set by the European RoHS 2.0 Directive 2011/65/EU & the European Delegated Directive (EU) 2015/863 on the restriction of the use of certain hazardous substances in electrical and electronic appliances.

**Directive 2012/19/EU (WEEE)**

We hereby declare that the products covered in this declaration meet the provisions of the WEEE Directive. B Medical Systems's obligation is to ensure the correct disposal of Electrical and Electronic Equipment (EEE) we produce when it reaches the end of its useful life and becomes waste.

**Regulation (EC) No 1005/2009 on substances that deplete the ozone layer**

We hereby declare that the products covered in this declaration are CFC and HCFC free, have no ozone depletion potential and therefore comply with the provisions of the Regulation (EC) No. 1005/2009. As insulating material polyurethane foam containing polyol, cyclopentane and isocyanate is used.

**Regulation (EU) No 517/2014 on fluorinated greenhouse gases**

We hereby declare that the products covered in this declaration are compliant to the provisions of the Regulation (EU) No 517/2014 on fluorinated greenhouse gases.

**DIN 58371:2010 and Önorm K 2030:2007 (Refrigerators for conserved blood)**

We hereby declare that the products covered in this declaration meet the requirements of DIN 58371:2010 and Önorm K 2030:2007.

**ISO 14644-1:2015 (Cleanrooms and associated controlled environments) and EU GMP Guidelines**

We hereby declare that the products covered in this declaration are manufactured according to good manufatcturing practices, do not generate primary particle emission and therefore may be used in clean rooms with following classifications:

Class ISO 6 / EC GMP B

medical systems
17, op der Hei
9809 Hosingen

Admilson Pinto
Quality Manager

Stamp and signature of approval holder
Issue date: 14.02.2018

Rev. 01