EU DECLARATION OF CONFORMITY

Manufacturer:	B Medical Systems S.à r.l. 17, op der Hei 9809 Hosingen Luxembourg
SRN:	LU-MF-000000128
Device description:	Blood bank refrigerators
GMDN Code:	35486
Basic UDI-DI:	05450104511059AW
Model names:	B401, B501, B701, B901
Catalog numbers:	991.8200.**, 991.8210.**, 991.8220.**, 991.8230.**
Intended purpose:	Blood bank refrigerators are devices intended to be used in the blood transfusion medicine for the support on the diagnosis, prevention and treatment of diseases or injuries by keeping whole blood or blood components (e.g., blood cells or plasma) at a protective and stable temperature until they are ready for use. The devices comprise a compression cooling system and 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.

Regulation (EU) 2017/745 of the European Parliament and of the Council

Class:	IIa
Classification rule:	Rule 2 acc. to the MDR (EU) 2017/745, Annex VIII – Non-invasive devices
Assessment:	Annex IX, Chapters I and III
Certificate No.:	G10 095256 0008
Validity:	19.05.2025
Notified body:	TÜV SÜD Product Service GmbH, N° 0123 Ridlerstraße, 65 D-80339 München

Directive 2014/35/EU (Low Voltage) / Directive 2006/42/EC (Machinery)

Applied standards:	EN 61010-1:2010 EN 61010-2-011:2017 IEC 61010-1:2010 (3rd Edition) IEC 61010-2-011:2016
Report No.:	244848-80083030, 244848-80058687_ATT1
Certificate No.:	CA26231M2CSA
Test Institute:	CSA Group Weismüllerstr. 45 D-60314 Frankfurt

Directive 2014/30/EU (EMC)

Applied standards:	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 61326-1:2012 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.:	0081/17, 0089/17, 0055/19, 0068/19, 0022/20
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.

ISO 14644-1 / ISO 14644-14 (Cleanrooms and associated controlled environments)

We hereby declare that the products covered in this declaration, when operated under the specified test conditions, are suitable for use in cleanrooms and fulfill the specifications of the below stated air cleanliness class according to ISO 14644-1.

Air Cleanliness Class:	4
Applied standards:	ISO 14644-1:2015, ISO 14644-14:2016
Report No.:	BM 2202-1300
Certificate No.:	BM 2202-1300_certificate_03, BM 2202-1300_statement_03
Test Institute:	Frauenhofer Institute for Manufacturing Engineering and Automation IPA Nobelstrasse 12 D-70569 Stuttgart

Admilson Pinto
Head of Quality Assurance

Stamp and signature of approval holder
Issue date: 22.06.2022

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