EU DECLARATION OF CONFORMITY

Manufacturer:	B Medical Systems S.à r.l. 17, op der Hei 9809 Hosingen Luxembourg
Product:	Laboratory freezers
GMDN Code:	15145
Models:	F400, F400W, F500, F500W, F700, F700W, F900, F900W
Basic UDI:	5450104543500, 5450104547621, 5450104543456, 5450104547638, 5450104543586, 5450104547560, 5450104543531, 5450104547645
Catalog number:	991.8800.**, 991.8802.**, 991.8810.**, 991.8812.**, 991.8820.**, 991.8822.**, 991.8830.**, 991.8832.**
Intended use:	Laboratory freezers are devices intended for the safe storage samples, specimens, live viris vaccines, cultures, test materials, chemicals, reagents and other laboratory preparations at temperatures below -20°C. The devices include an integrated alarm system that warns against unexpected temperature excursions and power failures.

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:	I
Classification rule:	Rule 2 acc. to the MDR (EU) 2017/745, Annex VIII – Non-invasive devices

Directive 2014/35/EU (Low Voltage)

Applied standards:	EN 61010-1:2010 EN 61010-2-011:2017 IEC 61010-1:2010 (3rd Edition) IEC 61010-2-011:2016
Report No.:	244848-80028277; 244848-80032090, 244848-80037379; 244848-80050997
Certificate No.:	CA23983M3CSA
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, 0090/17, 0091/17, 0092/17, 0055/19, 0068/19, 0029/20

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 on substances that deplete the ozone layer. 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 13221:2016 (Laboratory refrigerators and freezers)

We hereby declare that the products covered in this declaration meet the requirements of DIN 13221:2016.

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 5 / EC GMP A

medical systems

17, op der Hei

Admilson Pinto - 9809 Hosingen

Quality Manager

Stamp and signature of approval holder

Issue date: 12.11.2020

Rev. 02