medical systems

EU DECLARATION OF CONFORMITY

Manufacturer:	B Medical Systems S.à r.l. 17, op der Hei 9809 Hosingen Luxembourg
Product:	Contact Shock Freezers
GMDN Code:	61548
Model Names:	CSF61L, CSF61W, CSF61S, CSF101L, CSF101W, CSF101S
Basic UDI-DI:	05450104537912DH, 05450104540868CZ, 05450104540875CW, 05450104537936DX, 05450104540882CT, 05450104540899DC
Catalog number:	991.8900.**, 991.8910.**, 991.8920.**, 991.9000.**, 991.9010.**, 991.9020.**
Intended purpose:	Contact shock freezers are devices intended for the quick-freezing and subsequent temporary storage of blood plasma or biological samples to a core temperature below -30°C within less than one hour.

Digitally signed by Bolea Petru
Date: 2022.03.10 09:09:15 EET
Reason: MoldSign Signature
Location: Moldova

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 3 acc. to the MDR (EU) 2017/745, Annex VIII – Non-invasive products
Assessment:	Annex IX (excluding Section 5)
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)

Applied standards:	EN 61010-1:2010 EN 61010-2-011:2017 IEC 61010-1:2010 (3rd Edition) IEC 61010-2-011:2016
Certificate No.:	SE-93916M2
Report No.:	200018780UDI-CBS, 200018780UDI-CBS-R01,200018780UDI-CBS-R02
Test Institute:	Intertek Italia Spa Via Principe di Udine, 114 33030 Campoformido (UD)

Directive 2014/30/EU (EMC)

Applied standards:	EN 61326-1:2013 EN 61000-3-3:2013 EN 61000-3-11:2000 EN 61000-3-12:2011 IEC 61326-1:2012 IEC 61000-3-3:2013 IEC 61000-3-11:2017 IEC 61000-3-12:2011
Report No.:	200018908UDI-EMCa-R03
Test Institute:	Intertek Italia Spa Via Principe di Udine, 114 33030 Campoformido (UD)

Regulation (EC) No 1907/2006 (REACH)

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

Guideline for the collection of blood and blood components and the use of blood products, 2017

We hereby declare that the products covered by this declaration are compliant to the provisions of this Guideline *("Richtlinie Hämotherapie")* on the quick freezing of therapeutic plasma.

Guide to the preparation, use and quality assurance of blood components, EDQM 2017

We hereby declare that the products covered by this declaration are compliant to the provisions of this Guide on the quick freezing of plasma.

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

We hereby declare that the products covered by 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:

CSF..L models: Class ISO 6 / EC GMP B
CSF..W models: Class ISO 5 / EC GMP A

17, op der Hei
L - 9809 Hosingen

Admilson Pinto
Head of Quality Assurance

Stamp and signature of approval holder
Issue date: 19.08.2021

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