

## 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.

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 (3<sup>rd</sup> 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 Campofornido (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.

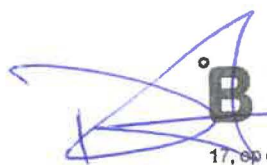


**ISO 14644-1:2015 (Cleanrooms and associated controlled environments) and EU GMP Guidelines**

We hereby declare that the products covered by this declaration are manufactured according to good manufacturing 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



**B** | medical  
systems  
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**Admilson Pinto**  
**Head of Quality Assurance**

Stamp and signature of approval holder  
Issue date: 19.08.2021

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