

## 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 Transport Boxes

**GMDN Code:** 62981

**CND Code:** V0499

**Basic UDI-DI:** 05450104511080AM

**Model names:** MT2  
MT4, MT4B, MT4-ET+4, MT4-ET+22, MT4-ET+37, MT4-ET-32  
MT8, MT8B, MT8-ET+4, MT8-ET+22, MT8-ET+37, MT8-ET-32  
MT12, MT12E, MT12-ET+4, MT12-ET-32  
MT25, MT25E, MT25-ET+4, MT25-ET+22, MT25-ET-32  
RCB4, RCB8, RCB12E, RCB12U, RCB25E, RCB25U

**Catalog numbers:** 991.5906.\*\*  
991.5920.\*\*, 991.5921.\*\*, 991.5925.\*\*  
958.4801.\*\*, 958.4804.\*\*, 958.4807.\*\*  
991.7705.\*\*, 991.7708.\*\*, 991.7712.\*\*  
991.1536.\*\*, 991.1539.\*\*, 991.1543.\*\*  
991.5923.\*\*, 958.4805.\*\*, 991.7709.\*\*, 991.7710.\*\*, 991.1540.\*\*, 991.1541.\*\*

**Intended purpose:** Blood transport boxes are thermal insulated containers intended for the safe transport of pre-conditioned whole blood or other blood components by use of frozen ice packs or PCMs as cooling elements.

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 products

**Assessment:** Annex IX (excluding Section 5)

**Certificate No.:** G 10 095256 0008 Rev.01

**Validity:** 19.05.2025

**Notified body:** TÜV SÜD Product Service GmbH, N° 0123  
Ridlerstraße, 65  
D-80339 München

**Directive 2008/68/EC on the inland transport of dangerous goods**  
**Directive 2002/84/EC on maritime safety and the prevention of pollution from ships**  
**European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR)**  
**Regulations Concerning the International Carriage of Dangerous Goods by Rail (RID)**  
**International Maritime Dangerous Goods Code (IMDG Code)**  
**IATA – Dangerous Goods Regulation (DGR)**  
**ICAO – Technical Instructions for the Safe Transport of Dangerous Goods by Air**

Applied standards: ADR Agreement, Part 6  
RID Regulations, Part 6  
IMDG Code, Part 6  
ICAO Technical Instructions, Part 6

Certificate No.: 150151, 150152, 150153, 150154, 150155

Report No.: G-08.153, G-11.059 H, G-08.154, G-11.060, G-08.156, G-11.061, G-08.157,  
G-11.062, G11.150

Test Institute: IBE-BVI  
Z1 Researchpark 280  
B-1731 Zellik (Asse)

The transport boxes are certified for the transport of dangerous goods of the following packing groups:

MT 2, MT 4\*, MT 12\*, RCB 4, RCB 12\*: packing groups I, II and III  
MT 8\*, MT 25\*, RCB 8, RCB 25\*: packing groups II and III

#### **Guide to the preparation, use and quality assurance of blood components**

European Committee (Partial Agreement) on Blood Transfusion {CD-P-TS}, European Directorate for the Quality of Medicines & HealthCare (EDQM), 15th Edition 2009 (published April 2010)

Applied standards: Chapter 5, Part A, Paragraph 1, 4. Storage and Transport  
Chapter 5, Part B, Paragraph 1-7, 4. Storage and Transport  
Chapter 5, Part C, Paragraph 1-9, 4. Storage and Transport  
Chapter 5, Part D, Paragraph 1-3, 4. Storage and Transport

Report No.: QB 103/2010, QB 104/2010, QB 105/2010, QB 106/2010

Test Institute: MedicOne Consulting GmbH  
Hammerstr. 176  
D-48153 Münster

The transport boxes using eutectic cooling elements (MT\*-ET\*) fulfill the requirements for the transport of blood components set forth by this European Guideline.

#### **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.

#### **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. 1005/200. As insulating material polyurethane foam containing polyol, cyclopentane and isocyanate is used.

  
  
Admilson Pinto, op der Hei  
- 9809 Hosingen  
Head of Quality Assurance

Stamp and signature of approval holder  
Issue date: 01.03.2022

Rev. 03