

EU Declaration of Conformity

Lmb Technologie GmbH Möslstr. 17 D-85445 Schwaig

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Declaration of Conformity

according to the Regulation (EU) 2017/745 on Medical Devices (MDR), Annex IV

Manufacturer: Lmb Technologie GmbH

Möslstr. 17

D-85445 Schwaig, Germany

Manufacturer's SRN: **DE-MF-000010761**

Basic UDI-DI: 40501710061F2

Product Name: **Donor Lounge Mobile**

Variants: **DL 100, DL 100P**

Product code: LM-10000, LM-20000

MDR Classification: Class I by Annex VIII, Rule 1

Notified Body name: N/A

Notified Body Address: N/A

Notified Body Identification number: N/A

Reference no. of certificate: N/A

Conformity assessment route: Following Article 52(7), the EU declaration of conformity is

issued after drawing up the technical documentation set

out in Annexes II and III.

The undersigned declares that the products described in this document meet the provision of the Regulation (EU) MDR 2017/745 for medical devices, Directive 2011/65/EU (RoHS2) amended with Directive (EU) 2015/863 and Directive (EU) 2017/2102 and relevant standards and common specifications as specified in the technical documentation. This declaration is supported by the Quality System approval to ISO 13485 issued by TÜV SÜD.

This EU Declaration is issued under the sole responsibility of the manufacturer.

Version: 1

Schwaig, 17.03.2023.

Place and date of issue

TECHNOLOGIE GMBH Miostraße 17

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Jelena Stanisavljevic, PRRC

This Declaration of Conformity is valid until withdrawn or reissued due to significant product change, new product code or new/changed regulatory/legal requirement.



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