Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) and
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	METRAX GmbH
Manufacturer address and contact details	Rheinwaldstraße 22 78628 Rottweil vigilance@primedic.com +49 741 257 - 0
Single Registration Number (SRN) (if available)	DE-MF-000005478

Notified body name	TÜV SÜD Product Service
Notified body number	0123
Directive Certificate number(s) to which this confirmation is made	G1 023787 0032 Rev. 01
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2024-05-26
End date of extended validity/transition period	2027-12-31

We, as the manufacturer declare under our sole responsibility:

- for the above mentioned **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate**

- Directive Certificate covering the listed devices were issued after 25 May 2017, was valid on 26 May 2021 and have not been withdrawn afterwards.
- Certificate Number: G1 023787 0032 Rev. 01

  https://www.tuvsud.com/ps-zert?q=G1+023787+0032+Rev.+01

Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body not later than 26 May 2024 for the substitute devices and a signed written agreement will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

A QMS in accordance with Article 10(9) MDR is in place.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with MDD.
- There are no significant changes in the design and intended purpose.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name:	METRAX GmbH
Location & Date:	Rottweil, 2024-03-17
Signature, Print Name, Title:	Heiko Borkowsky, Manager QM & RA

Metrax GmbH
Rheinwaldstr. 22 · 78628 Rottweil

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Devices**
PRIMEDIC HeartSave AED (M250)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]
PRIMEDIC HeartSave PAD (M250)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]
PRIMEDIC HeartSave AED-M (M250)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]
PRIMEDIC HeartSave AS (M250)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]
PRIMEDIC DefiMonitor XD [XD1 / XD1xe] (M290)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]
PRIMEDIC DefiMonitor XD PACER [XD10 / XD10xe] (M290)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]
PRIMEDIC DefiMonitor XD SPO2 [XD3 / XD3xe] (M290)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]
PRIMEDIC DefiMonitor XD SPO2, PACER [XD30 / XD30xe] (M290)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]
PRIMEDIC DefiMonitor XD AED [XD100 / XD100xe] (M290)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]
PRIMEDIC DefiMonitor XD AED, PACER [XD110 / XD110xe] (M290)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]
PRIMEDIC DefiMonitor XD AED, SPO2 [XD300 / XD300xe] (M290)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]
PRIMEDIC DefiMonitor XD AED, SPO2, PACER [XD330 / XD330xe] (M290)	G1 023787 0032 Rev. 01	2024-05-26	TÜV SÜD 0123	TÜV SÜD 0123	2027-12-31	HeartSave Y and HeartSave YA product family[1]

[1] The product family HeartSave Y and YA includes following models: HeartSave Y0, HeartSave Y1, HeartSave Y2, HeartSave Y3, HeartSave Y5, HeartSave Y6, HeartSave Y7, HeartSave Y8, HeartSave YA0, HeartSave YA1, HeartSave YA2, HeartSave YA3, HeartSave YA5, HeartSave YA6, HeartSave YA7, and HeartSave YA8