Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Technical Documentation Assessment Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter II
(Implantable Class IIb Devices and Class III Devices)

No. G70 023787 0039 Rev. 00

Manufacturer:

Metrax GmbH
Rheinwaldstr. 22
78628 Rottweil
GERMANY

SRN Manufacturer - DE-MF-000005478

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/745 on medical devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The technical documentation assessment included an assessment of the clinical evaluation assessment.
The conformity assessment has been carried out according to Annex IX chapter II of this regulation with a positive result.
Changes to the approved device, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device, shall require approval from the notified body TÜV SÜD Product Service GmbH.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX chapter I is necessary in addition to this EU Technical Documentation Assessment Certificate. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G70 023787 0039 Rev. 00

Report No.: 713347813

Valid from: 2025-05-12
Valid until: 2030-05-11

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-05-12

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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No. G70 023787 0039 Rev. 00

Classification:	Class III
Basic UDI-DI:	426064881myPADWC
Intended Purpose:	Devices are designed to be used in case of suspected sudden cardiac arrest, to guide the operator to start resuscitation, to analyze victim's ECG, to deliver defibrillation therapy through self-adhesive electrodes in case of a shockable rhythm and to guide the operator to perform cardiopulmonary resuscitation.
Device(s):	For device variants/models and parameters please see model list.

Device Basic UDI-DI: 426064881myPADWC

Model:	Model No.
HeartSave myPAD Semi-automated external defibrillator	HeartSave myPAD 670
HeartSave myPAD Semi-automated external defibrillator	HeartSave myPAD 671
HeartSave myPAD Semi-automated external defibrillator	HeartSave myPAD 675
HeartSave myPAD Semi-automated external defibrillator	HeartSave myPAD 678
HeartSave myPAD Fully-automated external defibrillator	HeartSave myPAD 670A
HeartSave myPAD Fully-automated external defibrillator	HeartSave myPAD 671A
HeartSave myPAD Fully-automated external defibrillator	HeartSave myPAD 675A
HeartSave myPAD Fully-automated external defibrillator	HeartSave myPAD 678A
DefiSign myPAD Semi-automated external defibrillator	DefiSign myPAD DS
DefiSign myPAD Fully-automated external defibrillator	DefiSign myPAD DSA
SafeLife myPAD Semi-automated external defibrillator	Safelife myPAD SL
SafeLife myPAD Fully-automated external defibrillator	Safelife myPAD SLA
BJÖRN myPAD Semi-automated external defibrillator	BJÖRN myPAD BSS
BJÖRN myPAD Semi-automated external defibrillator	BJÖRN myPAD BSD

The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History:

Rev.	Dated	Report	Description
00	2025-05-12	713347813	Initial issuance

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