PRIMEDIC Saves Life. Everywhere.	**Konformitätserklärung** **Declaration of Conformity**	Datum/Date: 7 April 2025

Metrax GmbH
Rheinwaldstr. 22
78628 Rottweil, Germany

Single Registration Number DE-MF-000005478

We hereby declare, on our own responsibility, the conformity of the below-named medical devices in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of April 5, 2017 concerning medical devices.

Defibrillation Mode	Model	CPR Sensor	WLAN	LTE	Display (for each model optional)	Metrax manufacturing number	Metrax sales number
Semi-automated external defibrillator (with shock button) **Basic-UDI-DI 426064881HSYKJ** **EMDN Z12030501**	HeartSave Y0	NO	NO	NO	NO	74250	97882
					YES	74283	97907
	HeartSave Y1	NO	YES	NO	NO	74251	97883
					YES	74284	97893
	HeartSave Y2	NO	NO	YES	NO	74252	97884
					YES	74285	97909
	HeartSave Y3	NO	YES	YES	NO	74253	97885
					YES	74286	97910
	HeartSave Y5	YES	NO	NO	NO	74250	97886
					YES	74283	97911
	HeartSave Y6	YES	YES	NO	NO	74251	97887
					YES	74284	97912
	HeartSave Y7	YES	NO	YES	NO	74252	97888
					YES	74285	97913
	HeartSave Y8	YES	YES	YES	NO	74253	97889
					YES	74286	97914
Fully-automated external defibrillator (without shock button) **Basic-UDI-DI 426064881HSYADY** **EMDN Z12030503**	HeartSave YA0	NO	NO	NO	NO	74254	97892
					YES	74287	97915
	HeartSave YA1	NO	YES	NO	NO	74255	97893
					YES	74288	97916
	HeartSave YA2	NO	NO	YES	NO	74256	97894
					YES	74289	97917
	HeartSave YA3	NO	YES	YES	NO	74257	97895
					YES	74290	97918
	HeartSave YA5	YES	NO	NO	NO	74254	97896
					YES	74287	97919
	HeartSave YA6	YES	YES	NO	NO	74255	97897
					YES	74288	97920
	HeartSave YA7	YES	NO	YES	NO	74256	97898
					YES	74289	97921
	HeartSave YA8	YES	YES	YES	NO	74257	97899
					YES	74290	97922

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Intended Use
HeartSave Y|YA 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.

Classification according to (EU) 2017/745 (MDR) Annex VIII:	**Class III, according to Rule 22**
Conformity assessment procedure:	**(EU) 2017/745 (MDR), Annex IX**
Notified Body	**TÜV SÜD Product Service GmbH** **Ridlerstraße 65, 80339 MÜNCHEN Germany** **CE 0123**
EU Technical Documentation Assessment Certificate	**G70 023787 0036**
EU Quality Management System Certificate	**G15 023787 0038**
Common specifications	None
The declaration of conformity is valid until 6 April 2030	

Rottweil,	7 April 2025	Metrax GmbH Rheinwaldstr. 22 · 78628 Rottweil
H. Borkowsky, QM/RA		