

**Metrax GmbH
Rheinwaldstr. 22
78628 Rottweil, Germany**

Single Registration Number DE-MF-000005478

We herewith declare that the products detailed within this declaration meet the requirements and provisions of the EU Medical Device Regulation 2017/745. All supporting documentation is retained on the premises of Metrax GmbH. Metrax GmbH assumes responsibility for compliance with the requirements of Regulation (EU) 2017/745, RED Directive 2014/53/EU and all other Union legislation applicable to the device. In addition, these products are in conformance with the provisions of Directive 2012/19/EU. In addition, the products listed herein are in conformance with the provisions of Council Directive 2011/65/EU as amended on the restriction of the use of certain hazardous substances in electrical and electronic equipment which apply to them.

Basic UDI-DI: 426064881myPADWC

Device Article Number	Catalogue (Order number with non-rechargeable battery)	Catalogue (Order number with rechargeable battery)	Name:	WLAN	LTE	CPR	EMDN
74261	97924	98071	HeartSave myPAD 670	NO	NO	NO	Z12030501
74261	97925	98072	HeartSave myPAD 670	NO	NO	YES	Z12030501
74334	97967	98073	HeartSave myPAD 670	YES	NO	NO	Z12030501
74334	97968	98074	HeartSave myPAD 670	YES	NO	YES	Z12030501
74335	97969	98075	HeartSave myPAD 670	NO	YES	NO	Z12030501
74335	97970	98076	HeartSave myPAD 670	NO	YES	YES	Z12030501
74336	97971	98077	HeartSave myPAD 670	YES	YES	NO	Z12030501
74336	97972	98078	HeartSave myPAD 670	YES	YES	YES	Z12030501
74262	97951	98079	HeartSave myPAD 671	NO	NO	NO	Z12030501
74262	97973	98080	HeartSave myPAD 671	NO	NO	YES	Z12030501
74337	97974	98081	HeartSave myPAD 671	YES	NO	NO	Z12030501
74337	97975	98082	HeartSave myPAD 671	YES	NO	YES	Z12030501
74338	97976	98083	HeartSave myPAD 671	NO	YES	NO	Z12030501
74338	97977	98084	HeartSave myPAD 671	NO	YES	YES	Z12030501
74339	97978	98085	HeartSave myPAD 671	YES	YES	NO	Z12030501
74339	97979	98086	HeartSave myPAD 671	YES	YES	YES	Z12030501
74263	97952	98087	HeartSave myPAD 675	NO	NO	NO	Z12030501
74263	97980	98088	HeartSave myPAD 675	NO	NO	YES	Z12030501
74340	97981	98089	HeartSave myPAD 675	YES	NO	NO	Z12030501
74340	97982	98090	HeartSave myPAD 675	YES	NO	YES	Z12030501
74341	97983	98091	HeartSave myPAD 675	NO	YES	NO	Z12030501
74341	97984	98092	HeartSave myPAD 675	NO	YES	YES	Z12030501
74342	97985	98093	HeartSave myPAD 675	YES	YES	NO	Z12030501
74342	97986	98094	HeartSave myPAD 675	YES	YES	YES	Z12030501
74264	97953	98095	HeartSave myPAD 678	NO	NO	NO	Z12030501
74264	97987	98096	HeartSave myPAD 678	NO	NO	YES	Z12030501
74343	97988	98097	HeartSave myPAD 678	YES	NO	NO	Z12030501
74343	97989	98098	HeartSave myPAD 678	YES	NO	YES	Z12030501
74344	97990	98099	HeartSave myPAD 678	NO	YES	NO	Z12030501



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**Konformitätserklärung
Declaration of Conformity**

Datum/Date:
12 May 2025

74344	97991	98100	HeartSave myPAD 678	NO	YES	YES	Z12030501
74345	97992	98101	HeartSave myPAD 678	YES	YES	NO	Z12030501
74345	97993	98102	HeartSave myPAD 678	YES	YES	YES	Z12030501
74265	97954	98103	HeartSave myPAD 670A	NO	NO	NO	Z12030503
74265	97994	98104	HeartSave myPAD 670A	NO	NO	YES	Z12030503
74346	97995	98105	HeartSave myPAD 670A	YES	NO	NO	Z12030503
74346	97996	98106	HeartSave myPAD 670A	YES	NO	YES	Z12030503
74347	97997	98107	HeartSave myPAD 670A	NO	YES	NO	Z12030503
74347	97998	98108	HeartSave myPAD 670A	NO	YES	YES	Z12030503
74348	97999	98109	HeartSave myPAD 670A	YES	YES	NO	Z12030503
74348	98000	98110	HeartSave myPAD 670A	YES	YES	YES	Z12030503
74266	97955	98111	HeartSave myPAD 671A	NO	NO	NO	Z12030503
74266	98002	98112	HeartSave myPAD 671A	NO	NO	YES	Z12030503
74349	98003	98113	HeartSave myPAD 671A	YES	NO	NO	Z12030503
74349	98004	98114	HeartSave myPAD 671A	YES	NO	YES	Z12030503
74350	98005	98115	HeartSave myPAD 671A	NO	YES	NO	Z12030503
74350	98006	98116	HeartSave myPAD 671A	NO	YES	YES	Z12030503
74351	98007	98117	HeartSave myPAD 671A	YES	YES	NO	Z12030503
74351	98008	98118	HeartSave myPAD 671A	YES	YES	YES	Z12030503
74267	97956	98119	HeartSave myPAD 675A	NO	NO	NO	Z12030503
74267	98009	98120	HeartSave myPAD 675A	NO	NO	YES	Z12030503
74352	98010	98121	HeartSave myPAD 675A	YES	NO	NO	Z12030503
74352	98011	98122	HeartSave myPAD 675A	YES	NO	YES	Z12030503
74353	98012	98123	HeartSave myPAD 675A	NO	YES	NO	Z12030503
74353	98013	98124	HeartSave myPAD 675A	NO	YES	YES	Z12030503
74354	98014	98125	HeartSave myPAD 675A	YES	YES	NO	Z12030503
74354	98015	98126	HeartSave myPAD 675A	YES	YES	YES	Z12030503
74268	97957	98127	HeartSave myPAD 678A	NO	NO	NO	Z12030503
74268	98016	98128	HeartSave myPAD 678A	NO	NO	YES	Z12030503
74355	98017	98129	HeartSave myPAD 678A	YES	NO	NO	Z12030503
74355	98018	98130	HeartSave myPAD 678A	YES	NO	YES	Z12030503
74356	98019	98131	HeartSave myPAD 678A	NO	YES	NO	Z12030503
74356	98020	98132	HeartSave myPAD 678A	NO	YES	YES	Z12030503
74357	98021	98133	HeartSave myPAD 678A	YES	YES	NO	Z12030503
74357	98022	98134	HeartSave myPAD 678A	YES	YES	YES	Z12030503
74276	98023	98135	DefiSign myPAD DS	NO	NO	NO	Z12030501
74276	98024	98136	DefiSign myPAD DS	NO	NO	YES	Z12030501
74358	98025	98137	DefiSign myPAD DS	YES	NO	NO	Z12030501
74358	98026	98138	DefiSign myPAD DS	YES	NO	YES	Z12030501
74359	98027	98139	DefiSign myPAD DS	NO	YES	NO	Z12030501
74359	98028	98140	DefiSign myPAD DS	NO	YES	YES	Z12030501
74360	98029	98141	DefiSign myPAD DS	YES	YES	NO	Z12030501
74360	98030	98142	DefiSign myPAD DS	YES	YES	YES	Z12030501
74277	98031	98143	DefiSign myPAD DSA	NO	NO	NO	Z12030503
74277	98032	98144	DefiSign myPAD DSA	NO	NO	YES	Z12030503
74361	98033	98145	DefiSign myPAD DSA	YES	NO	NO	Z12030503
74361	98034	98146	DefiSign myPAD DSA	YES	NO	YES	Z12030503
74362	98035	98147	DefiSign myPAD DSA	NO	YES	NO	Z12030503
74362	98036	98148	DefiSign myPAD DSA	NO	YES	YES	Z12030503
74363	98037	98149	DefiSign myPAD DSA	YES	YES	NO	Z12030503
74363	98038	98150	DefiSign myPAD DSA	YES	YES	YES	Z12030503
74278	98039	98151	SafeLife myPAD SL	NO	NO	NO	Z12030501
74278	98040	98152	SafeLife myPAD SL	NO	NO	YES	Z12030501
74364	98041	98153	SafeLife myPAD SL	YES	NO	NO	Z12030501
74364	98042	98154	SafeLife myPAD SL	YES	NO	YES	Z12030501
74365	98043	98155	SafeLife myPAD SL	NO	YES	NO	Z12030501
74365	98044	98156	SafeLife myPAD SL	NO	YES	YES	Z12030501
74366	98045	98157	SafeLife myPAD SL	YES	YES	NO	Z12030501
74366	98046	98158	SafeLife myPAD SL	YES	YES	YES	Z12030501
74279	98047	98159	SafeLife myPAD SLA	NO	NO	NO	Z12030503
74279	98048	98160	SafeLife myPAD SLA	NO	NO	YES	Z12030503
74367	98049	98161	SafeLife myPAD SLA	YES	NO	NO	Z12030503
74367	98050	98162	SafeLife myPAD SLA	YES	NO	YES	Z12030503
74368	98051	98163	SafeLife myPAD SLA	NO	YES	NO	Z12030503



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74368	98052	98164	SafeLife myPAD SLA	NO	YES	YES	Z12030503
74369	98053	98165	SafeLife myPAD SLA	YES	YES	NO	Z12030503
74369	98054	98166	SafeLife myPAD SLA	YES	YES	YES	Z12030503
74280	98055	98167	BJÖRN myPAD BSS	NO	NO	NO	Z12030501
74280	98056	98168	BJÖRN myPAD BSS	NO	NO	YES	Z12030501
74370	98057	98169	BJÖRN myPAD BSS	YES	NO	NO	Z12030501
74370	98058	98170	BJÖRN myPAD BSS	YES	NO	YES	Z12030501
74371	98059	98171	BJÖRN myPAD BSS	NO	YES	NO	Z12030501
74371	98060	98172	BJÖRN myPAD BSS	NO	YES	YES	Z12030501
74372	98061	98173	BJÖRN myPAD BSS	YES	YES	NO	Z12030501
74372	98062	98174	BJÖRN myPAD BSS	YES	YES	YES	Z12030501
74281	98063	98175	BJÖRN myPAD BSD	NO	NO	NO	Z12030501
74281	98064	98176	BJÖRN myPAD BSD	NO	NO	YES	Z12030501
74373	98065	98177	BJÖRN myPAD BSD	YES	NO	NO	Z12030501
74373	98066	98178	BJÖRN myPAD BSD	YES	NO	YES	Z12030501
74374	98067	98179	BJÖRN myPAD BSD	NO	YES	NO	Z12030501
74374	98068	98180	BJÖRN myPAD BSD	NO	YES	YES	Z12030501
74375	98069	98181	BJÖRN myPAD BSD	YES	YES	NO	Z12030501
74375	98070	98182	BJÖRN myPAD BSD	YES	YES	YES	Z12030501

Intended Use

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 0039
EU Quality Management System Certificate	G15 023787 0038
Common specifications (CS)	None

The declaration of conformity is valid until 11 May 2030

Rottweil,	12 May 2025	 
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H. Borkowsky, QM/RA