EU DECLARATION OF CONFORMITY

Manufacturer Name	A.M.I. Italia S.r.l.		
Registered Office Address	Viale Campi Flegrei n.55, 80124 Napoli ITALIA		
Operation Sites	• Via Cupa Reginella 15/A, 80010 Quarto (NA) – Italy • Via San Francesco a Patria SNC Località Ponte Riccio - Zona ASl-80014 Giugliano (NA) – Italy		
Single Registration Number	IT-MF-000016770		
Product Category	External Cardiac Defibrillators, Fully Automatic and Semi-Automatic		
Trade Name of Family-1	SaverOne, SaverOne S1, GeoSaver		
Trade Name of Family-2	SMARTY Saver, SMARTY SaverTech, SMARTY SaverPlus, SMARTY SaverGeo		
Trade Mark	AMI Italia		
Intended Use	The intended use of External Cardiac Defibrillator is the detection of the electrocardiogram with consequent cardiac defibrillation via electric shock, in the event that ventricular tachycardia or ventricular fibrillation is detected. They are intended and used to stop ventricular fibrillation and pulseless ventricular tachycardia.		
Unique Identification Code (UDI)	Refer Attachment-1		
Basic UDI-DI	**Trade Name of Family-1**	**Model No.**	**Basic UDI**
	GeoSaver	SGS-B0988 SGS-B0989 SGA-B0990 SGA-B0991	++G159GEOSAVER9T
		SGD-B0992 SGD-B0992-U SGD-B0992-Q SGD-B0992-U-Q SGD-B0993 SGD-B0993-U SGD-B0993-Q SGD-B0993-U-Q	++G159GEOSAVERDJN
		SGP-B0994 SGP-B0994-U SGP-B0994-Q	++G159GEOSAVERPKE

		SGP-B0994-U-Q SGP-B0995 SGP-B0995-U SGP-B0995-Q SGP-B0995-U-Q	
	SaverOne	SVO-B0918 SVO-B0919 SVO-B0001 SVO-B0002 SVO-B0847 SVO-B0848	++G159SAVERONEFH
		SVD-B0004 SVD-B0004-U SVD-B0004-Q SVD-B0004-U-Q SVD-B0005 SVD-B0005-U SVD-B0005-Q SVD-B0005-U-Q	++G159SAVERONEDTF
		SVP-B0006 SVP-B0006-U SVP-B0006-Q SVP-B0006-U-Q SVP-B0007 SVP-B0007-U SVP-B0007-Q SVP-B0007-U-Q	++G159SAVERONEPU7
	SaverOne S1	S1S-B0978 S1S-B0979 S1B-B0980 S1B-B0981 S1A-B0982 S1A-B0983	++G159SAVERONES1AQ
		S1D-B0984 S1D-B0984-U S1D-B0984-Q S1D-B0984-U-Q S1D-B0985 S1D-B0985-U S1D-B0985-Q S1D-B0985-U-Q	++G159SAVERONEDS1WV
		S1P-B0986 S1P-B0986-U S1P-B0986-Q S1P-B0986-U-Q S1P-B0987 S1P-B0987-U S1P-B0987-Q S1P-B0987-U-Q	++G159SAVERONEPS1YR

	Trade Name of Family-2	Model No.	Basic UDI
	SMARTY Saver	SM1-B1001 SM2-B1002	++G159SMARTYSAVERBX
	SMARTY SaverTech	SMB-B0001 SMA-B0002	++G159SMARTYSAVERBX
	SMARTY SaverPlus	SM3-B1003 SM4-B1004	++G159SMARTYSAVERPLUS8P
	SMARTY SaverGeo	SM5-B1005 SM6-B1006	++G159SMARTYSAVERGEOLF
EMDN	Z12030501: Semi Automatic Defibrillators Z12030503: Automatic Defibrilators		
MDA Codes	MDA 0305		
Risk Classification	Class III, Rule 22		
Conformity Assessment Route	As per Annex IX chapters I, II and III of the MDR 2017/745		
Applicable Standards	EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN 60601-1:2006+A1:2013+ AC:2014 +A12: 2014 +A2: 2020, EN 60601-1-2:2015+A1:2020, EN 60601-1-8:2007+AC: 2014+A11: 2017 +A2:2020, EN 60601-1-11:2015+ A1: 2020, EN 60601-1-12:2015+ A1: 2020, EN 60601-2-4:2011+ A1: 2019, EN 60601-2-27:2014, EN 60601-2-47:2015, EN 62304:2006/ A1:2015, EN IEC 60086-4:2019, IEC 60529:1989/AMD2:2013/ COR1 :2019, EN 1064:2020, EN 60601-1-6:2010+A1:2015 + A2:2020, EN 62366-1:2015+AC:2015 +AC: 2016+A1:2020, EN ISO 15223-1:2021, EN 20417:2021, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2018, EN ISO 10993-23:2021, EN ISO 17664-1:2021		
Guidelines	MEDDEV 2.7.1:2016 (Rev4), MDCG 2018-1 Rev.4, MDCG 2018-4, MDCG 2019-1, MDCG 2019-4, MDCG 2019-5, MDCG 2019-9, MDCG 2020-5, MDCG 2020-6, MDCG 2020-7, MDCG 2020-8, MDCG 2020-10/1, MDCG 2020-13, MDCG 2020-15, MDCG 2021-1 Rev.1, MDCG 2021-5, MDCG 2021-19, MDCG 2021-24		
Directives	ETSI EN 301 489-1 (V2.1.1): 02-2017, ETSI EN 301 489-19 Draft (V2.1.0) : 03-2017, ETSI EN 301 489-7 V1.3.1 (2005-11), ETSI EN 301 489-52 V1.1.0 (2016-11), EN 62311:2008 - Article 3.1a -HEALTH, ETSI EN 301 489-17 V3.2.4 (2020-09) BT - Article 3.1b - EMC, ANSI/AAMI EC57:2012, ANSI/AAMI DF39:1993, 2012/19/EU (WEEE) on waste electrical and electronic equipment DIRECTIVE 2011/65/EU		
Notified Body	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A., Via Quintiliano 43 20138 Milano – ITALY, NB No.: 0051		
EC Certificate(s)	No. 168/MDR No. 169/MDR		

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Single Registration Number	IT-MF-000016770	
Product Category	Disposable External Defibrillation Pads	
Trade Name with Models	**Trade Name**	**Model**
	SaverOne-GeoSaver-SaverOne S1 Adult Electrode Pads	SAV-C0846
	Smarty SaverTech Adult Electrode Pads	SMT-C1846
	SaverOne-GeoSaver-SaverOne S1 Paediatric Electrode Pads	SAV-C0016
	Smarty SaverTech Paediatric Electrode Pads	SMT-C1016
	SaverOne-GeoSaver-SaverOne S1 F/F Adult/Paediatric Electrode Pads	SAV-C0599
	Smarty Saver F/F Adult/Paediatric Electrode Pads	SMT-C2002
	Smarty Saver Adult/Paediatric Electrode Pads	SMT-C2001
	SaverOne-GeoSaver-SaverOne S1 Electrodes for ECG Cable	SAV-C0952
	SaverOne-GeoSaver-SaverOne S1 ECG patient cable	SAV-C0017
Trade Mark	AMI Italia	
Intended Use	Defibrillation paddles are primarily intended for the treatment of patients with ventricular cardiac fibrillation in combination with a defibrillator device.	
Unique Identification Code (UDI)	Refer Attachment-1	
Basic UDI-DI	++G159PADTH	
EMDN	C020401-External Cardioversion Defibrillator Electrode Pads	
Risk Classification	Class III, Rule 22	
Conformity Assessment Route	As per Annex IX chapters I, II and III of the MDR 2017/745	
Applicable Standards	EN ISO 13485:2016/A11:2021, EN ISO 14971:2019/A11:2021, EN 60601-1:2006+A1:2013+ AC:2014 +A12: 2014 +A2: 2020, EN 60601-1-2:2015+A1:2020, EN 60601-1-8:2007+AC: 2014+A11: 2017 +A2:2020, EN 60601-1-11:2015+ A1: 2020, EN 60601-1-12:2015+ A1: 2020, EN 60601-2-4:2011+ A1: 2019, EN ISO 10993-1:2020, EN ISO 10993-5:2009, EN ISO 10993-10:2021, EN ISO 10993-11:2018, EN ISO 10993-23:2021	
Guidelines	MEDDEV 2.7.1:2016 (Rev4), MDCG 2018-1 Rev.4, MDCG 2018-4, MDCG 2019-1, MDCG 2019-4, MDCG 2019-5, MDCG 2019-9	

	MDCG 2020-5, MDCG 2020-6, MDCG 2020-7, MDCG 2020-8, MDCG 2020-10/1, MDCG 2020-13, MDCG 2020-15, MDCG 2021-1 Rev.1, MDCG 2021-5, MDCG 2021-19, MDCG 2021-24
Directives	ETSI EN 301 489-1 (V2.1.1): 02-2017, ETSI EN 301 489-19 Draft (V2.1.0) : 03-2017, ETSI EN 301 489-7 V1.3.1 (2005-11), ETSI EN 301 489-52 V1.1.0 (2016-11), EN 62311:2008 - Article 3.1a - HEALTH, ETSI EN 301 489-17 V3.2.4 (2020-09) BT - Article 3.1b - EMC, ANSI/AAMI EC57:2012, ANSI/AAMI DF39:1993, 2012/19/EU (WEEE) on waste electrical and electronic equipment, DIRECTIVE 2011/65/EU
Notified Body	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A., Via Quintiliano 43 20138 Milano – ITALY, NB No.: 0051
EC Certificate(s)	No. 168/MDR No. 169/MDR

We declare that the manufacturer is solely responsible for;

- This declaration is at the sole discretion of A.M.I Italia S.r.l.
- We A.M.I Italia S.r.l declare that the above-mentioned products meet the provisions of the REGULATION (EU) 2017/745, all prior amendments and as transposed into national laws in relevant Union legislation. All supporting documentation is retained under the premises of the manufacturer.
- The conformity assessment is in accordance with the procedure as documented in Annex IX of the REGULATION (EU) 2017/745.
- The manufacturing facility fulfills the requirements of EN ISO 13485:2016/A11:2021

Place & Date of Issue:	02.12.2024 Napoli, Italia
Signature: (Name & Designation)	 Sergio Arbitrio, CEO