Identification of the Legal Manufacturer:	Appsens AS Senterveien 30 N-4790 Lillesand, Norway
This Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer.	
Declaration:	We declare the EU Declaration of Conformity is issued under the sole responsibility of the Legal Manufacturer Appsens AS. We declare under our sole responsibility that the product detailed below is in accordance with directive 93/42/EEC, as amended by 2007/47/CE, following Annex II excluding section 4, and in accordance with directive 2011/65/EU.
Unique Device Identifier (UDI):	EUDAMED registration: B- NOMF000013438ECG247P9 ECG247 Smart Heart Sensor System EMDN nomenclature code: Code Z12050403 ECG HOLTER RECORDERS Product UDI-DI codes: B-7090052220009SS ECG247 Smart Sensor and Electrode B-7090052220030SH ECG247 APP B-7090052220047T2 ECG247 Back-end Cloud Service B-7022750045004SF ECG247 Smart Sensor (Norway) B-7022750045035SS ECG247 Electrode patch (Norway) B-7090052220085TA ECG247 Sensore Cardiaco (Italia) B-7090052220115SS ECG247 Electrode Patch (Europe) B-7090052220054SX ECG247 Smart Heart Sensor B-7090052220061SU ECG247 Smart Heart Sensor and Electrode Patch
Identification of the device(s) concerned:	**Electrocardiographic long-term ambulatory recorder system and belonging software** Including: • ECG247 Smart Sensor (GMDN 38729), Model: 353 010 • ECG247 Electrode (GMDN 62597), Model: 353 010 • ECG247 APP (GMDN 62169) • ECG247 Smart Sensor Software Solution (GMDN 41651)
Risk Classification:	Class IIa. Medical Device Directive (93/42/EEC), Annex IX, Chapter III, Rule 10.
Relevant Harmonized Standards	NEK EN 60601-1:2006/A2:2021 NEK IEC 60601-1-2:2014+A1:2020 NEK IEC 60601-1-6:2010+A1:2013+A2:2020 NEK IEC 60601-1-11:2015+A1:2020v NEK EN 60601-2-47:2015 IEC 60601-4-2:2016 NEK IEC 60529:1989/A2:2013/COR1:2019 NEK EN 62304:2006/AMD1:2015 CSV NEK IEC 62366-1:2015+A1:2020 NEK EN 82304-1:2017 SN-CEN ISO/TS 82304-2:2021 NS-EN ISO 14971:2019/A11:2021 ISO 10993-1:2020, 5:2009, 10:2013

	Directive 2011/65/EU (RoHS2) MEDDEV 2.7/1 revision 4
Name and address of Notified Body:	# 0197 TÜV Rheinland Polska Sp. z o.o ul. Wielicka 250, 30-663 Kraków, Poland
Applicable CE Certificate(s):	EC Quality System Certificate No. 10000366191-PA-NA-NOR Rev.0.0, issued by the DNV GL PRESAFE AS Notified Body Number 2460, in accordance with Annex II Section 3.2 of Directive 93/42/EEC with Confirmation letter based on 120.3c of MRD (EU) 2023/607 for transitional provisions APPSE_PLAQ1_HZ_2024_01_19_signed.pdf /84965583 from TÛV Rheinland, LGA.
Date of first CE Marking (using NB # 2460):	November 03, 2020
Identification of the person authorized to sign on behalf of Legal Manufacturer:	Name: Legal Name of Authorized Signatory Signature: Tord Ytterdahl _____ Title: Director of Regulatory Affairs, CEO Place of Issue: Lillesand, Norway Date: September 19, 2024

Revision History

Rev	*Date mm/dd/yy*	*DCN*	*What changed?*	*Why did it change?*	*Author*
A	10/26/19	19/0-A	Initial release	Based on product specification	R.Fensli
1.2	01/20/20	20/1-2	Declaration statement	Supplemented standards	R.Fensli
1.3	04/20/20	20/1-3	Corrected product name	According to final labelling	R.Fensli
1.4	05/12/20	20/1-4	Corrected “Modell nr.” to “Model:”	Language correction	R.Fensli
1.5	10/20/20	20/1-5	Corrected system name	Harmonized documents	R.Fensli
1.6	11/05/20	20/1-6	Updated CE Certificate details	CE-conformance from Presafe	R.Fensli
1.7	11/20/21	21/1-7	Updated revised standards	New standards published	R.Fensli
1.8	09/15/22	22/1-8	Updated revised standards	New standards published	R.Fensli
1.9	28/10/22	22/1-9	Updated list of product UDI and EUDAMED registration number. Updated name of Notified Body	New registration in EUDAMED and new product codes. Notified Body changed the registered name	R.Fensli
1.10	02/08/24	24/1-10	Updates GMDN numbers	Chanes in GMDN coding system	R.Fensli
1.11	02/19/24	24/1-11	Updated NB and transitional provisions	After transfer from DMV GL to TÛV	R.Fensli