




## DECLARATION OF CONFORMITY

Identification of the Legal Manufacturer:	 <p>Appsens AS Bergshaven 17 N-4790 Lillesand, Norway</p>
Declaration:	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):	GTIB 7090052220009
Identification of the device(s) concerned:	<p><b>Electrocardiographic long-term ambulatory recorder system and belonging software</b></p> <p>Including:</p> <ul style="list-style-type: none"> <li>• ECG247 Smart Sensor (GMDN 44423), Model: 353 010</li> <li>• ECG247 Electrode (GMDN 62597), Model: 353 010</li> <li>• ECG247 APP (GMDN 59378)</li> <li>• ECG247 Smart Sensor Software Solution (GMDN 41651)</li> </ul>
Risk Classification:	Class IIa. Medical Device Directive (93/42/EEC), Annex IX, Chapter III, Rule 10.
Relevant Harmonized Standards	<p>NEK EN 60601-1:2006; A1:2012          NEK EN 60601-1-2:2015          IEC 60601-1-6:2010; AMD1:2013          NEK IEC 60601-1-11:2015          IEC 60601-2-47:2012          IEC 60601-4-2:2016          IEC 60529:1989(AMD2:2013)          NEK EN 62304:2006          NEK IEC 62366:2015/COR1:2016          NEK EN 82304-1:2017          NS-EN ISO 14971:2012          ISO 10993-1:2009, 5:2009, 10:2010          Directive 2011/65/EU (RoHS2)          MEDDEV 2.7/1 revision 4</p>
Name and address of Notified Body:	DNV GL PRESAFE AS, Notified Body NO.: 2460
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
Date of first CE Marking (using NB # 2460):	November 03, 2020
Identification of the person authorized to sign on behalf of Legal Manufacturer:	<p>Name: Legal Name of Authorized Signatory</p> <p>Signature: Tord Ytterdahl _____</p> <p>Title: Director of Regulatory Affairs, CEO</p> <p>Place of Issue: Lillesand, Norway</p> <p>Date: November 04, 2020</p>