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CVR. nr. 63644919

EC Declaration of Conformity No.: REG-003791

Product Name	Ambu® aView™ 2 Advance	
REF	405011000	
Identification of the Device	Category: Type: Software ver.:	Medical Device Accessory Displaying Unit v1.0.0 or v1.0.1

Identification: All products manufactured after issue date.

We, the manufacturer, hereby declare that the device(s) covered by the present declaration is in conformity with the requirements specified in the relevant Union legislation:

Council directive 93/42/EEC, Annex I and Annex VII enforced in Danish law.

Device classification: Class I, non-sterile according to Annex IX, rule 12

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011
on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS recast) as is specified in Article 4.
RoHS category of device: Category 8 – Medical devices

Radio Equipment Directive 2014/53/EU

Article 3.1(a) Health & Safety	EN 62311: 2008
Article 3.1(b) EMC	EN 301 489-1 v2.1.1 EN 301 489-17 v3.1.1 EN 55032:2015 + AC:2016, Class A EN 61000-3-2:2014 EN 61000-3-3:2013 EN 61000-4-2:2009 EN 61000-4-3:2006 + A1:2008 + A2:2010 EN 61000-4-4:2012 EN 61000-4-5:2014 + A1:2017 EN 61000-4-6:2014 + AC:2015 EN 61000-4-11:2004 + A1:2017
Article 3.2 Spectrum	EN 300 328 v2.1.1 EN 301 893 v2.1.1

Signed for and on behalf of Ambu A/S, Denmark

25 Jan 2020

Kristine Rasmussen, Head of Regulatory Affairs Innovation

First Issued: 01 May 2020

EC Declaration of Conformity – Annex I: GMDN Code

No.: REG-003791

Product Name: Ambu® aView™ 2 Advance

The Ambu® aView™ 2 Advance are covered by the following GMDN Code:

GMDN Code:56654
Term: Endoscopic video image display monitor