

## EU Declaration of Conformity

No.: REG-004660

### We

Manufacturer: Ambu A/S  
Single Registration number DK-MF-000001437  
Postal address: Baltorpbakken 13  
City, country: 2750, Ballerup, Denmark  
Telephone number: +45 72252000  
E-mail address: ambu@ambu.com

### declare that the declaration is issued under the sole responsibility and belongs to the following devices:

Product name Ambu® WhiteSensor 40713  
Ambu® WhiteSensor 40554  
Ambu® WhiteSensor 40556  
Intended purpose ECG Electrodes  
Catalogue number(s) 40713  
40554  
40556  
Device risk class Class I (rule I, Annex VIII)  
Basic UDI-DI 570748030100520257Z  
GMDN code and term 17460, Neonatal Electrocardiograph electrode

### The devices covered by the present declaration is in conformity with the requirements specified in the relevant Union legislation:

Medical Device Regulation 2017/745  
Restriction of Hazardous Substances Directive (2011/65/EU)

### Conformity assessment procedure:

Class I, non-sterile: Annex II and III

### Signed for and behalf of Amby A/S:

Ballerup, Denmark 2021-05-25  
Place of issue Date of issue



Kristine Rasmussen, Head of Regulatory Affairs  
Innovation, Corporate RA

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