

EU Declaration of Conformity

No.: REG-003958

We

Manufacturer: Ambu A/S
Single Registration number: DK-MF-000001437
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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® aScope™ 4 Broncho
Intended purpose: Flexible endoscope for single use
Catalogue numbers: 476001000
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478001000
Device risk class: Class IIa (rule 6, Annex VIII)
Basic UDI-DI: 570748030002010005S
GMDN code and term: 60963, Flexible video bronchoscope, single-use

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), 2011 as amended by Commission Delegated Directive (EU) 2015/863
Electromagnetic Compatibility Directive (2014/30/EU)

Conformity assessment procedure:

Class IIa: Annex IX (Chapter I and section 4)

Notified body:

Name of Notified body: BSI
Certificate: MDR 722402

Notified Body number: 2797

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Affairs

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