

EU Declaration of Conformity

No.: REG-004386

We

Manufacturer: Ambu A/S
Single Registration number: DK-MF-000001437
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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® Perfit ACE™, Ambu® Mini Perfit ACE™, Ambu® Military Perfit ACE™
Intended purpose: The Ambu Perfit ACE is a one-piece rigid cervical spine immobilization device designed to assist the rescuer with the maintenance of neutral alignment, prevention of lateral (side-to-side) sway and anterior-posterior (forward and backward) flexion and extension of the cervical spine during patient transport or movement.
Catalogue number(s): 002810001
264208020
000281107
Device risk class: Class I (rule 1, Annex VIII)
Basic UDI-DI: 5707480301000050065
GMDN code and term: 45129
Cervical spine collar, 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

Conformity assessment procedure:

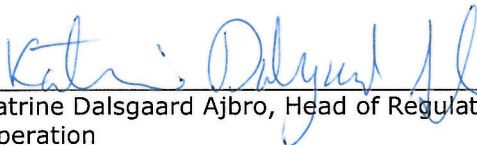
Class I, non-sterile: Annex II and III,

Signed for and behalf of Amby A/S:

Ballerup, Denmark 2021-02-23

[place of issue]

[Date of issue]


Katrine Dalsgaard Ajbros, Head of Regulatory Affairs
Operation

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