

## EU Declaration of Conformity

No.: REG-004386

### We

Manufacturer: Ambu A/S  
Single Registration number: Currently not available  
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® 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 [1] (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  
[place of issue]

2021-01-28  
[Date of issue]

Katrine Dalsgaard Ajbro, Head of Regulatory Affairs  
Operation

First issue: 2021-01-28