

## EC Declaration of Conformity

**No.: REG-001249**

**Product Name:** Ambu® AuraOnce™ – Single Use Laryngeal Mask - Sterile

<b>REF and Configuration</b>	Size #1:	321 100 000,	321 100 000U (US)
	Size #1 <sup>1/2</sup> :	321 150 000,	321 150 000U (US)
	Size #2:	321 200 000,	321 200 000U (US)
	Size #2 <sup>1/2</sup> :	321 250 000,	321 250 000U (US)
	Size #3:	321 300 000,	321 300 000U (US)
	Size #4:	321 400 000,	321 400 000U (US)
	Size #5:	321 500 000,	321 500 000U (US)
	Size #6:	321 600 000,	321 600 000U (US)

**Accessory:** None

**Identification:** All products manufactured after the issue date.

**We the manufacturer hereby declare that this product is in conformity with the requirements in:**

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

Equipment class: IIa, sterile, Annex IX rule 5

**and in accordance with the authorization given by BSI Certificate No. CE 68734.**

**For and on behalf of Ambu A/S, Denmark**

17 October  
2018



Kaja Tengbjerg, Director, Corporate Regulatory Affairs

**First Issued: 3 January 2014**

**EC Declaration of Conformity – Annex I: GMDN Code**

**No.: REG-001249**

**Product Name:**

The Ambu® AuraOnce™ – Single Use Laryngeal Mask – Sterile are covered by the following GMDN Code:

**GMDN Code:** 45036

**Term:** Airway, laryngeal, single-use