

Declaration of conformity Medical Devices, class Is

Legal Manufacturer:	Abena A/S Egelund 35 DK 6200 Aabenraa
Conformity assessment procedure	Annex VII for Technical documentation and Annex V for sterilization procedure of the Medical Devices Directive 93/42/EEC as amended by the Council Directive 2007/47/EEC.
Notified body number	0543
Classification and harmonized standards	Class 1s, sterile, Annex IX, Rule 4 EN 14079
Product	Curi-Med Nonwoven swabs, Y-cut Art.no. 221605, 221606, 221607
We, the legal manufacturer hereby declare that the above-mentioned product complies with the European Medical Device Directive 93/42/EEC as amended by the Council Directive 2007/47/EEC and its relevant transposition into all national laws of the member states into which we place the devices. Signed in Aabenraa 02.11.2017	
Oigned in Adbellida	02.11.2017
Name and authority	Kasper Haick Lundsgaard Global Category Manager
Signature	longe in hoff

Date:

12-07-2016 Document responsible: Annika Matzen

Page 1 of 1

Version:

09

Approved by:

Annika Matzen

Updated by:

AMA

Doc. no. and name:

2.0.3S Declaration of Conformity, Class Is