GETINGE

EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Doc ID: GD10128
Revision: A

acc. to Article 19 of Regulation (EU) 2017/745 on Medical Devices

Name and Address of the Manufacturer:	Getinge Disinfection AB Ljungadalsgatan 11 352 46 Växjö, Sweden
Single Registration Number:	SE-MF-000001012

On our sole responsibility, we hereby declare that the product(s)

Product- / Trade Name:	Getinge Aquadis 56
Description:	The intended use of this washer-disinfector, including approved accessories, is to clean, disinfect and dry reusable medical items. The device is not intended to clean and disinfect invasive devices as end-point processing.
Classification (acc. to Annex VIII):	Class IIa

Product Name	Product Model	Basic UDI-DI
Getinge Aquadis 56	56M, 56A	73401537000484

comply with the relevant provisions of the following Regulation(s) and Directive(s):

Regulation (EU) 2017/745 on Medical Devices

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany. CE 0123
Conformity Assessment Procedure:	Acc. to Annex IX without chapter II of Regulation (EU) 2017/745
EC Certificate:	No. G10 102669 0006 Rev. 00
Common Specifications used:	N/A

The product also complies with the requirements of the Machinery Directive 2006/42/EG, Low Voltage Directive 2014/35/EU, RoHS 2011/65 including 2015/863/EU and EMC Directive 2014/30/EU

GETINGE

EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

Doc ID: GD10128
Revision: A

acc. to Article 19 of Regulation (EU) 2017/745 on Medical Devices

This declaration of conformity is valid from date of issue until 2026-05-17.

Växjö, 2021-12-07

Anna Eklöf-Persson, Managing Director

Signed on behalf of Getinge Disinfection AB