

# EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

acc. to Directive 93/42/EEC on Medical Devices (The Swedish impl. Act  
SFS 1993:584, Ordinance: SFS 1993:876, Regulation: LVFS 2013:11)

Doc ID: GD8673  
Rev: F

**Name and Address of the Manufacturer:** Getinge Disinfection AB,  
Ljungadalsgatan 11, 35246 Växjö, Sweden

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

**Product Description:** Washer Disinfector  
**Product-No.:** See list below  
**Classification** (acc. to Annex IX of MDD): Class IIb  
comply with the relevant provisions of the following Directive(s): **Directive 93/42/EEC on Medical Devices**  
**Notified Body:** TÜV SÜD Product Service GmbH  
Ridlerstraße 65, 80339 Munich, Germany.  
CE 0123  
**Conformity Assessment Procedure:** Acc. to Annex II excluding (4) of Directive  
93/42/EEC  
**EC certificate:** No. G1 102669 0003 Rev. 01

The product also complies with the requirements of the Machinery Directive 2006/42/EG, Low Voltage Directive 2014/35/EU, RoHS 2011/65/EU on the restriction of the use of certain substances in electrical and electronic equipment and EMC Directive 2014/30/EU.

This declaration of conformity is valid from date of issue until 26<sup>th</sup> of May, 2024

Product Name	Product Model
Getinge WD 14 Tablo	GE14
Getinge WD 15 Claro	GE15
Getinge 46-Series	46-4, 46-5
Getinge 86-Series	S-8666, S-8668, S-8668T
Getinge 9100-Series	9120E, 9122EW, 9125E, 9127E, 9128E, 9128EW
Getinge CM320-Series	CM320

Växjö, 10<sup>th</sup> of Dec, 2021

Anna Eklöf-Persson, Managing Director  
Signed on behalf of Getinge Disinfection AB

Getinge Disinfection AB  
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