

Issued by:
RA Madeleine Gloy
Date:
2014-08-29

Reg. No.
GD2310 EN
Revision C

EC Declaration of Conformity

Getinge Disinfection AB hereby declares that medical devices described below comply with the requirements of the European Medical Devices Directive 93/42/EEC (LVFS 2003:11), Machine Directive 2006/42/EG, Low Voltage Directive (LVD) 2006/95/EC and RoHS2 (2011/65/EU).
LVFS 2003:11 is the Swedish implementation of MDD 93/42/EEC.

Compliance with the MDD 93/42/EEC annex II has been audited and validated by the Notified Body Intertek SEMKO AB, Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden.
Code 0413. Certificate No: 41314824.

Washer Disinfectors. These medical devices are part of class IIb.

| <u>Name</u> | <u>Model</u> | <u>GMDN code</u> |
|----------------------|--------------------------|------------------|
| Getinge WD 14 Tablo | GE14 | 17671 |
| Getinge WD 15 Claro | GE15 | 17671 |
| Getinge 46-Series | 46-4, 46-5, 46-4T, 46-5T | 17671 |
| Getinge 86-Series | S-8666, S-8668 | 17671 |
| Getinge 88-Series | 88-5 | 17671 |
| Getinge 9100-Series | 9120, 9122, 9125, 9128 | 17671 |
| Getinge CM320-Series | CM320 | 17671 |

Washer Disinfectors. This medical device is part of class IIa.

| <u>Name</u> | <u>Model</u> | <u>GMDN code</u> |
|---------------------|--------------|------------------|
| Getinge 9000-Series | 9027 | 17671 |

Washer Disinfectors for human waste containers. These medical devices are part of class IIa.

| <u>Name</u> | <u>Model</u> | <u>GMDN code</u> |
|---------------------|---|------------------|
| Getinge 600-Series | S-607, S-608, Amigo | 35318 |
| Getinge 1600-Series | FD 1600, FD 1605, FD 1610, FD 1615, Ninjo | 35318 |
| Getinge 1800-Series | FD 1800, FD1805, FD 1810, Tornado | 35318 |
| Getinge 6000 | SP-6000, Typhoon | 35318 |

Växjö 2014-08-29
Getinge Disinfection AB



Philip Nokrach
Quality Assurance & Regulatory Affairs Manager