

EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

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

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Name and Address of the Manufacturer: Quadralene Limited, Bateman Street,
Derby, DE23 8JL
Single Registration Number: GB-MF-000016550.

Name and Address of the Authorised Representative: Maquet GmbH, Kehler Strasse 31, 76437
Rastatt, Germany
Single Registration Number: DE-AR-000009120.

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

Product- / Trade Name: Getinge Neutralizer
Description: Neutralising additive for addition to intermediate stages of a washer disinfectant process when reprocessing medical devices.
Reference-No.: XV1476
Basic UDI-DI (acc. to Part C of Annex VI): 506047811XV14766E
Classification (acc. to Annex VIII): Class I

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

Regulation (EU) 2017/745 on Medical Devices

Conformity Assessment Procedure: acc. to Annex II and Annex III of Regulation (EU) 2017/745
Common Specifications used: N/A

This declaration of conformity is valid from date of issue until 25th May 2026.

Derby, 15th November 2021



Clare Clark, Quality and Regulatory Manager
Signed on behalf of Quadralene Ltd.

The products can be delivered in the following variants / with the following components:

Product Description	Product-No.	Basic UDI-DI
Getinge Neutralizer 5L	503435831	506047811XV14766E
Getinge Neutralizer 10L	503435931	506047811XV14766E
Getinge Neutralizer 10L	503435932	506047811XV14766E
Getinge Neutralizer 10L	503435933	506047811XV14766E
Getinge Neutralizer 10L	503435934	506047811XV14766E
Getinge Neutralizer 25L	503436031	506047811XV14766E
Getinge Neutralizer 25L	503436032	506047811XV14766E
Getinge Neutralizer 25L	503436033	506047811XV14766E
Getinge Neutralizer 25L	503436034	506047811XV14766E
Getinge Neutralizer 205L	503436131	506047811XV14766E