

EU DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

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

Doc ID: DOCG-10

Revision: 2

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 Universal Detergent
Description: Mild alkaline detergent for washer-disinfector, ultrasonic baths and manual cleaning of medical and surgical instruments.
Reference-No.: XV1610
Basic UDI-DI (acc. to Part C of Annex VI): 506047811XV16105S
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

A handwritten signature in blue ink, consisting of a series of loops and a long horizontal stroke.

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 Universal Detergent 5L	6001692431	506047811XV16105S
Getinge Universal Detergent 10L	6001692531	506047811XV16105S
Getinge Universal Detergent 10L	6001692532	506047811XV16105S
Getinge Universal Detergent 10L	6001692533	506047811XV16105S
Getinge Universal Detergent 10L	6001692534	506047811XV16105S
Getinge Universal Detergent 25L	6001692631	506047811XV16105S
Getinge Universal Detergent 25L	6001692632	506047811XV16105S
Getinge Universal Detergent 25L	6001692633	506047811XV16105S
Getinge Universal Detergent 25L	6001692634	506047811XV16105S
Getinge Universal Detergent 205L	6001692731	506047811XV16105S