

Declaration of Conformity

We hereby declare that the medical device, due to its design and the version we have placed on the market, complies with the basic requirements of Regulation (EU) 2017/745 considering article 120 (3). The manufacturer is solely responsible for issuing this declaration of conformity.

Manufacturer	METASYS Medizintechnik GmbH Florianistrasse 3, 6063 Rum bei Innsbruck, Austria
SRN	AT-MF-000014438
Basic UDI-DI	++D98410010K6
Product trade name	GREEN&CLEAN WK
Article number / product designation	see Annex I
Intended purpose	Solution for disinfection and elimination of germs in water-bearing pipes in treatment units.
Classification	Risk class IIa (according to regulation (EU) 2017/745 Annex VIII)
Applied common specifications and other Union standards / legislations	see Annex 2
Notified body	TÜV NORD CERT GmbH (CE0044)
Certificate number	44 911 220982 valid until 08/08/2029
Conformity assessment	Regulation (EU) 2017/745, Article 19 and Annex II, III

Place, date
Rum, 08.08.2024


Bruno Pregoner
Managing Director

Valid from: 08.08.2024

Valid until: Until the change of one of the products specified in Annex I, but at the latest until: 08.08.2029

Annex I - List of article numbers

UDI-DI - article number - product trade name

+D9841120000380 - 112000038 - GREEN&CLEAN WK 750 ml
+D9841120000390 - 112000039 - GREEN&CLEAN WK 1000 ml
+D9841120000480 - 112000048 - GREEN&CLEAN WK ATMOS 1000 ml
+D9841120000391 - 122000056 - GREEN&CLEAN WK 1000 ml, 6 bottles
+D9841120000381 - 122000057 - GREEN&CLEAN WK 750 ml, 4 bottles
+D9841120000481 - 122000058 - GREEN&CLEAN WK ATMOS 1000 ml, 6 bottles

Annex II - Applied common specifications and other Union standards / legislations

This present declaration is also in conformity with the following Union standards/legislations and Common Specifications (CS):

Applied common specifications

not applicable

Standard/Legislation - Description

EN 13623 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity against Legionella of chemical disinfectants for aqueous systems - Test method and requirements