

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	++D98410008KK
Product trade name	GREEN&CLEAN M2
Article number / product designation	see Annex I
Intended purpose	GREEN&CLEAN M2 is a dual, active defoaming concentrate for cleaning, disinfection and deodorization of suction pipes of dental suction systems.
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 Pregenzer
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

+D9841120000240 - 112000024 - GREEN&CLEAN M2 green 500 ml
+D9841120000250 - 112000025 - GREEN&CLEAN M2 red 500 ml
+D9841120000241 - 122000030 - GREEN&CLEAN M2 green 500 ml, 25 bottles
+D9841120000251 - 122000031 - GREEN&CLEAN M2 red 500 ml, 25 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 13727 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements

EN 13624 - Chemical disinfectants and antiseptics - Quantitative suspension test for the determination of fungicidal or levurocidal activity in the field of human medicine - Test method and requirements

EN 14348 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements

EN 14561 - Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements

EN 14562 - Chemical disinfectants and antiseptics - Quantitative microbial carrier test for the evaluation of fungicidal or levurocidal activity for instruments used in the medical area - Test method and requirements

EN 14476 - Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements

ISO/TS 15883-5 - Washer-disinfectors Part 5: Test soils and methods for demonstrating cleaning efficacy