


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 Florianstrasse 3, 6063 Rum bei Innsbruck, Austria
SRN	AT-MF-000014438
Basic UDI-DI	++D98410023KF
Product trade name	MULTI SYSTEM TYP 1
Article number / product designation	see Annex I
Intended purpose	The MULTI SYSTEM TYP 1 is a two-stage single-place amalgam separator with integrated air/water separation and place selection valve for separating amalgam from waste water from dental treatment units.
Classification	Risk class I (according to regulation (EU) 2017/745 Annex VIII)
Applied common specifications and other Union standards / legislations	see Annex 2
Notified body	not applicable
Certificate number	not applicable
Conformity assessment	Regulation (EU) 2017/745, Article 19 and Annex II, III

Place, date
Rum, 15.04.2024


Bruno Pregenzer
Managing Director

Valid from: 15.04.2024

Valid until: Until the change of one of the products specified in Annex I, but at the latest until: 15.04.2029

Annex I - List of article numbers

Article number, designation of the product, scope of delivery

- 101000001 - MST 1, amalgam separator with standard accessories and instructions for use
- 101000002 - MST 1, KaVo, amalgam separator with KaVo accessories and instructions for use
- 101000003 - MST 1, Ultradent, amalgam separator with Ultradent accessories and instructions for use
- 101000004 - MST 1, Finndent, amalgam separator with Finndent accessories and instructions for use
- 101000005 - MST 1, Planmeca, amalgam separator with PlanMeca accessories and instructions for use
- 101000006 - MST 1, Castellini, amalgam separator with Castellini accessories and instructions for use
- 101000007 - MST 1, Beistellgerät, amalgam separator with cover, standard accessories and instructions for use
- 101000008 - MST 1, OMS, amalgam separator with OMS accessories and instructions for use
- 101000009 - MST 1, Eur MED, amalgam separator with EurMED accessories and instructions for use
- 101000010 - MST 1, CEFLA, amalgam separator with CEFLA accessories and instructions for use
- 101000011 - MST 1, Module 1, 2, 3, amalgam separator without accessories and instructions for use
- 101000012 - MST 1, FR, amalgam separator with standard accessories and instructions for use (only available in France)
- 101000013 - MST 1, FR, amalgam separator with cover, standard accessories and instructions for use (only available in France)

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/CS - Description

not applicable