

EU DECLARATION OF CONFORMITY

according to Medical Device regulation (EU) 2017/745 and
according to Low Voltage directive 2014/35/EU and
according to EMC directive 2014/30/EU and
according to RoHS directive 2011/65/EU and
according to REACH directive 1907/2006/EU and
according to Eco-Design framework directive 2009/125/EC and
according to WEEE directive 2012/19/EU

We as manufacturer: **flow-med GmbH, Weinbergweg 10, 73773 Aichwald, Germany**

SRN: **DE-MF-000006336**

declare under our responsibility that the following listed medical devices meet all applicable basic safety and performance requirements of the regulations mentioned above.

Product name: **u-sonic 3**
Item number: **604 00000**
Basic UDI-DI: **4260277010066P**
EMDN: **Y214580**
Intended use: **Electronic ultrasonic cleansing station for ear molds and dentals**
Product classification: **Class 1, according to annex VIII, rule 1 and 13 of regulation (EU) 2017/745 (MDR)**
Applied specifications/ norms: **EN 55022:2010, EN 55024:2010, EN 63000:2018**



Valid until:
31.12.2025

Aichwald, 01.01.2024

Place, date

CE

MD

Name Managing Director:
Meiko Panitzsch

Signature

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medical appliances

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