

EC DECLARATION OF CONFORMITY

This Declaration of conformity is issued under the sole responsibility of the manufacturer

Manufacture:

J. MORITA MFG. CORP.

680 Higashihama Minami-cho, Fushimi-ku, Kyoto 612-8533, Japan

SRN: JP-MF-000023000

EU authorized representative:

Medical Technology Promedt Consulting GmbH

Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany

SRN: DE-AR-000000085

Device Model

BASIC UDI-DI: 4548213000B0005DV

Description: Dental Handpiece maintenance unit

Product name: Lubricare 2

Model name: HIM-2

Type: BA

Product code: K345BIA

Intended purpose:

HIM-2 is used for lubrication and cleaning the dental handpieces or surgical handpieces.

Risk class: Class I, Rule 13

Conformity assessment procedure: Regulation EU 2017/745 Clause 52, section7

Complied regulations and Directives

We declare that this device is in compliance with:

Regulation (EU) 2017/745:

Medical Device Regulation

Directive 2011/65/EU:

RoHS 2 Directive

Directive 2006/42/EC:

Machinery Directive

Applied CS: None

Signed for and on behalf of: J. MORITA MFG. CORP.

Date / Place:

2024.6.6 /Kyoto, Japan

Signature: Yoshihiko Takashima Managing Director

Yoshihiko Takashima

Revision history

No.	Date	Reason/Detail
0	2021-01-26	First edition.
1	2021-12-20	SRN, Conformity assessment procedure and Directive added.
2	2022-10-07	The address of the EU Authorized Representative has changed. Regulation and revision history added.
3	2023-12-25	BASIC UDI-DI changed.
4	2024-06-05	Corrected the product code.