EC Declaration of Conformity according to Annex IV
Medical Device Regulation 2017/745/EU

KAVO

Manufacturer

KaVo Dental GmbH
Bismarckring 39
88400 Biberach
Germany
www.kavo.com

EUDAMED SRN DE-MF-000006471

Product / REF

EXPERTsurg LUX / 1.008.3500
MASTERsurg LUX Wireless / 1.009.1200
SM5 / 1.011.4900

Basic UDI-DI ++EKAVG512Z8

Classification Class IIa, Rule 9

Intended use of the product (s)
This KaVo product is intended only for use in the field of dentistry, for surgery to expose and dissect oral tissue structures or endodontic treatments (e.g. periodontal gap, gingiva, bone, jaw, extractions, implantations) and must be used by expert medical staff only. Any other type of use is not permitted.
For detailed description of product and accessories see instructions for use

EC Marking in accordance with
Regulation on medical devices (MDR) 2017/745/EU

Common Specifications
Currently not available

Statement
We declare under our sole responsibility that the products manufactured by us to which this declaration relates conform to the essential safety and performance requirements in accordance with the provisions of the above directives and their applicable annexes.

This declaration is supported by the certificate with registration no. 51512-60-00-00 according to the Conformity assessment procedure of Directive 2017/745/EU, Annex IX.

Notified Body 2017/745/EU
DEKRA Certification GmbH
Handwerkstrasse 15
70565 Stuttgart
0124

Validity
Issued on 2024-05-24
Valid until 2026-09-28

Klaus Reisenauer
Senior Director Regulatory Affairs
Quality Assurance