

**EU Declaration of conformity
for medical devices
according to Regulation (EU) 2017/745**



Name of manufacturer: **Warmińska Sp. z o.o.**

Single registration number (SRN): **PL-MF-000004324**

Address: **ul. Wysokiej Bramy 31, 11-100 Lidzbark Warmiński, Poland**

Product name: **Medizinische Kappe**

Models: **FALA**

Basic UDI-DI: **5904208959falaL8**

Trading names: **OP-Hauben, blau**

OP-Hauben, grün

Risk class: **I, acc. rule 1**

Intended use: **Cap for use by medical assistants to ensure hygienic safety during medical procedures**

I declare that the above products meet the requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (...).

The conformity assessment procedure was based on the development of technical documentation according to Annexes II and III of the abovementioned Regulation.

The EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Place and date	Issued (name, surname, position, signature) * incl. indication for, and on behalf of whom, that person signed)
Lidzbark Warmiński, 11.03.2022	Agnieszka Wasilewska Person Responsible for Regulatory Compliance On behalf of the CEO 