POLISH CENTRE FOR
TESTING AND CERTIFICATION

CERTIFICATE

No. 1434-MDR-012/2024

of Conformity of the Quality Management System EU with the requirements of Chapters I and III of the Annex IX to the Regulation (EU) 2017/745 issued to manufacturer:

SMS Sp. z o.o.
Adamowicza 8, 05-530 Góra Kalwaria, Poland
Single Registration Number (SRN): PL-MF-000010604

Polish Centre for Testing and Certification S.A. (Notified Body no. 1434) certifies that the manufacturer has established, documented and implemented a Quality Management System as described in article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details of the devices covered by this certificate are described on the following pages. The Report referenced below summarizes the result of the assessment and includes reference to the relevant common specifications, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapters I and III to the regulation mentioned above. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected a on representative sample. The certified Quality Management System is subject to periodical surveillance by PCBC S.A. The surveillance assessment shall also include an assessment of the technical documentation for the devices concerned on the basis of further representative samples.

Report no.: **S/042/BM/2023**

Validity of the Certificate: from 30.01.2025 to 29.01.2030
The date of issue of the Certificate: 30.01.2025

Tomasz Kozłov
Head of Medical Devices
Certification Department

Certificate bears the qualified signature PCBC S.A.
Warsaw, 30/01/2025

Polish Centre for Testing and Certification 469, Puławska Street, PL-02-844 Warsaw tel.: +48 22 45 46 200, pcbc@pcbc.gov.pl

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No. 1434-MDR-012/2024

of Conformity of the Quality Management System EU with the requirements of Chapters I and III of the Annex IX to the Regulation (EU) 2017/745

Devices covered by the certificate:

Low temperature hydrogen peroxide gas-plasma sterilizer P50

Risk Classification: IIa

EMDN Code: Z12011309

Certificate validity conditions and/or limitations: N/A

Revision History including Changes: 1 / 30.01.2025 / S/042/BM/2023

Certificate bears the qualified signature PCBC S.A.
Warsaw, 30/01/2025

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