

EC Certificate Full Quality Assurance System: Certificate PL04/61068

The management system of

## SMS Sp. z o.o.

ul. Konstruktorska 8, 02-673 Warszawa, Poland

has been assessed and certified as meeting the requirements of

### Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

**Large Steam Sterilisers for medical use:**

- AS 66 range (LUMO 66 range), (DGM AND-300, DGM AND-400, DGM AND-600, DGM AND-800)
- AS 44 range (LUMO 44 range) (DGM AND-100, DGM AND-150)
- AS 366 range (LUMO 366 range)

**Duże sterylizatory parowe do użytku medycznego:**

- typu AS 66 (typu LUMO 66), (DGM AND-300, DGM AND-400, DGM AND-600, DGM AND-800)
- typu AS 44 (typu LUMO 44) (DGM AND-100, DGM AND-150)
- typu AS 366 (typu LUMO 366)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 21 January 2016 until 11 January 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 13 November 2018  
Issue 15. Certified since 12 January 2004

Certification is based on reports numbered PL/WAW PL00102

Authorised by

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Page 1 of 1

