

MEDICAL DEVICES DIRECTIVE 2017/745

DECLARATION OF CONFORMITY



THERMOMAT saniline S.r.l. whose premises are in Via M. Curie, 7 – 46034 Borgo Virgilio – Mantova (Italy) being represented by Ms. Rossella Ragazzi (legal representative) declares under her own responsibility that the following products:

HANDRAILS AND SHOWER SYSTEM

classified in class I Medical Devices complies with the Essential Requirements of Medical Devices Directive 2017/745

| MODELS | | | | | | | | |
|----------------------------------|----------|----------|----------|-------------------------------|----------|----------|----------|--|
| LINEAR HANDRAILS ELEGANCE | | | | SAFETY SHOWER ELEGANCE | | | | |
| ELMA40BC | ELMA50BC | ELMA60BC | ELMA90BC | ELSHDOCB | ELSHDOCN | ELSHDOCC | | |
| ELMA40NR | ELMA50NR | ELMA60NR | ELMA90NR | ELSHTCSD | ELSHTCSD | ELSHTCSD | ELSHTNSD | |
| | | | | B | N | C | N | |
| | | | | | | | | |
| | | | | | | | | |

Applied evaluation procedure 2017/745 (in attachment)

The application of the conformity procedure is testified by the presence on the packaging of the label with the mark. The products covered by this declaration conform to the following technical norms:

- UNI EN 12182 – Technical aids for disabled people: general requirements and test methods;
- UNI CEI EN ISO 14971 – Application of the risk management to medical devices;
- UNI EN 1041 – Information released by the manufacturer together with the medical devices;
- CND 2018 – Nomenclature of the medical devices.

Borgo Virgilio, 07/04/2020

ROSSELLA
RAGAZZI
Stamp and signature
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