

# 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 GRABRAILS - classified in class I Medical Devices


complies with the Essential Requirements of Medical Devices Directive 2017/745

MODELS (all finishes)			
<b>LINEAR HANDRAILS AND GRABRAILS</b>			
M30	M45	M60	M90
M120	M150	M180	M200
110	MAS	MAD	120
121	122	123	124
132	142	152	162
172	182	200	210
201	211	250	260
270	280	CSM	CSMAG
320	310	MAR	

<b>VERTICAL HANDRAILS</b>	
330	300

<b>MODULAR HANDRAILS</b>	
--------------------------	--

Applied evaluation procedure 2017/745 Directive

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;
- Nomenclature of the medical devices.

Borgo Virgilio, 07/04/2020

Rossella Ragazzi  
Stamp and signature  
