

MEDICAL DEVICES DIRECTIVE 2017/745

DECLARATION OF CONFORMITY




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

SUPPORTING BARS - classified in class I Medical Devices

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

MODELS (all finishes)									
FOLDING SUPPORT BARS				WALL FIXED SUPPORTING BARS				WALL/FLOOR FIXED SUPPORTING BARS	
600	830	840	650	601	602	831	832	800	
850	860	640	660						
600-E	830-E	640-E	840-E						
603-E									

Applied evaluation procedure Directive 2017/745

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.

Virgilio, 07/04/2020

Rossella Ragazzi
Stamp and signature
THERMOMAT SANILINE S.R.L.
VIA M. CURIE, 7 - 46034 BORGOVIRGILIO (MANTOVA)
P. IVA 07907070201