

EC Declaration of Conformity

S.I.L.C. S.p.A., Strada Provinciale nr.35, km.4 , 26017 Trescore Cremasco (Cremona - Italia) email: info@silcitalia.com PEC: silcdirezione@legalmail.it as 'legal manufacturer' indemnified with Eudamed code SRN IT-MF-000010693

DECLARES

That the following Medical Devices:

Product Code	Description
00990	SOFFISOF BED PADS EXTRA 60X90_6X15 PCS
00991	SOFFISOF BED PADS EXTRA 80X180_6X15 PCS
00992	SOFFISOF BED PADS SUPER 40X60_16X15 PCS
00993	SOFFISOF BED PADS SUPER 60X60_12X15 PCS
00994	SOFFISOF BED PADS SUPER 60X90_6X15 PCS
00995	SOFFISOF BED PADS SUPER 80X180_6X15 PCS
00996	SOFFISOF BED PADS EXTRA 60X90_4X30 PCS
00997	SOFFISOF BED PADS EXTRA 80X180_4X30 PCS

- are identified with Basic UDI-DI: 8007300FAM0000009Z6
- satisfy all essential requisites set in Annex I 'General safety and performance requirements' of Reg. UE 745/ 2017 (MDR)
- belong to the class I according to the rules of classification stated in Annex VIII
- are non-sterile and are marketed in non-sterile packaging
- are not measuring instruments
- are not intended for clinical studies

The manufacturer is committed to preserve and make available to health authorities the technical documentation, as specified in Annex II of the above regulation for 10 years as from the last production date of the item.

All supporting documentation is retained at the premises of the manufacturer

The manufacturer declares that the medical devices will be placed on the market with CE mark according to Annex V and Art.20 MDR

Trescore Cremasco (CR), 05/01/2023

Signature
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Dott. Cesare Battaglia
CEO