Sede: Strada Provinciale n.35 Km 4
26017 TRESCORE CREMASCO (CR) Italy
Centr.Tel.: 0373 271.1 r.a.
Uff.Comm.: Fax 0373 273922
Uff. Amm.: Fax 0373 274762
Posta PEC: silcdirezione@legalmail.it
Fatturazione PEC: efatturasilc@legalmail.it

Cap. Sociale € 15.000.000 i.v.
Iscr. Reg. Impr. di Cremona e
Cod. Fisc./P.IVA 00163160195
R.E.A. Cremona N° 90991
Cod. Meccan. CR 002722
VAT IT 00163160195
www.silc.it - E-mail: info@silcitalia.com

EU 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
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
00998	SOFFISOF BED PADS EXTRA 60X90_6X15 PCS
00999	SOFFISOF BED PADS EXTRA 80X180_6X15 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 rule 1 of classification stated in Annex VIII
- are non-sterile and are marketed in non-sterile packaging
- are not measuring instruments
- are not invasive medical devices
- are not intended for clinical studies or for diagnostic purpose
- are single use devices
- acts as a protective layer to be placed on a surface or beneath a user so to absorb urine and feces
- not designed to be used together with other medical devices.

Sede: Strada Provinciale n.35 Km 4
26017 TRESCORE CREMASCO (CR) Italy
Centr.Tel.: 0373 271.1 r.a.
Uff.Comm.: Fax 0373 273922
Uff. Amm.: Fax 0373 274762
Posta PEC: silcdirezione@legalmail.it
Fatturazione PEC: efatturasilc@legalmail.it

Cap. Sociale € 15.000.000 i.v.
Iscr. Reg. Impr. di Cremona e
Cod. Fisc./P.IVA 00163160195
R.E.A. Cremona N° 90991
Cod. Meccan. CR 002722
VAT IT 00163160195
www.silc.it - E-mail: info@silcitalia.com

The manufacturer is committed to preserve and make available to health authorities the technical documentation, as specified in Annex II and in Annex III 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), 04/12/2023

Signature

.....

Dott. Cesare Battaglia

CEO