

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
00912	SOFFISOF AIR DRY PANTS EXTRA SIZE SMALL 6X14 PCS
02858	SOFFISOF AIR DRY PANTS PLUS SIZE MEDIUM 6X14 PCS
02859	SOFFISOF AIR DRY PANTS PLUS SIZE LARGE 6X14 PCS
02860	SOFFISOF AIR DRY PANTS EXTRA SIZE MEDIUM 6X14 PCS
02861	SOFFISOF AIR DRY PANTS EXTRA SIZE LARGE 6X14 PCS
02863	SOFFISOF AIR DRY PANTS SUPER SIZE MEDIUM 4X10 PCS
02864	SOFFISOF AIR DRY PANTS SUPER SIZE LARGE 4X10 PCS
02866	SOFFISOF AIR DRY PANTS MAXI SIZE MEDIUM 4X8 PCS
02867	SOFFISOF AIR DRY PANTS MAXI SIZE LARGE 4X8 PCS
02868	SOFFISOF AIR DRY PANTS EXTRA SIZE MEDIUM 4X9 PCS
02869	SOFFISOF AIR DRY PANTS EXTRA SIZE LARGE 4X8 PCS
02872	SOFFISOF AIR DRY PANTS EXTRA SIZE XLARGE 4X12 PCS
02873	SOFFISOF AIR DRY PANTS SUPER SIZE XLARGE 4X8 PCS
02874	SOFFISOF AIR DRY PANTS SUPER SIZE MEDIUM 4X9 PCS
02875	SOFFISOF AIR DRY PANTS SUPER SIZE LARGE 4X8 PCS

- are identified with Basic UDI-DI: 8007300FAM0000001YN
- 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
- not to be worn on open wounds
- not designed to be used together with other medical devices.



Sede: Strada Provinciale n.35 Km 4
26017 TRESORE 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), 27/09/2024

Signature
.....
Dott. Cesare Battaglia
CEO

A large, stylized handwritten signature in black ink, written over a dotted line. The signature is cursive and fluid, with a long horizontal stroke extending to the right.