

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 AIR DRY BRIEFS
01115	SOFFISOF BRIEFS AIR DRY EXTRA SIZE SMALL 6X15 PCS
01116	SOFFISOF BRIEFS AIR DRY EXTRA SIZE MEDIUM 6X15 PCS
01117	SOFFISOF BRIEFS AIR DRY EXTRA SIZE LARGE 6X15 PCS
01118	SOFFISOF BRIEFS AIR DRY SUPER SIZE MEDIUM 6X15 PCS
01034	SOFFISOF BRIEFS AIR DRY SUPER PLUS SIZE MEDIUM 6X15 PCS
01119	SOFFISOF BRIEFS AIR DRY SUPER SIZE LARGE 6X15 PCS
01035	SOFFISOF BRIEFS AIR DRY SUPER PLUS SIZE LARGE 6X15 PCS
01120	SOFFISOF BRIEFS AIR DRY SUPER SIZE XLARGE 4X15 PCS
01121	SOFFISOF BRIEFS AIR DRY MAXI SIZE MEDIUM 4X15 PCS
01036	SOFFISOF BRIEFS AIR DRY MAXI SUPER SIZE MEDIUM 4X15 PCS
01122	SOFFISOF BRIEFS AIR DRY MAXI SIZE LARGE 4X15 PCS
01037	SOFFISOF BRIEFS AIR DRY MAXI SUPER SIZE LARGE 4X15 PCS
01123	SOFFISOF BRIEFS AIR DRY MAXI SIZE XXLARGE 4X15 PCS
01124	SOFFISOF BRIEFS AIR DRY MAXI SIZE XXXLARGE 4X15 PCS
01125	SOFFISOF BRIEFS AIR DRY MAXI PLUS SIZE SMALL 6X15 PCS
01126	SOFFISOF BRIEFS AIR DRY MAXI PLUS SIZE MEDIUM 4X15 PCS
01127	SOFFISOF BRIEFS AIR DRY MAXI PLUS SIZE LARGE 4X15 PCS
01128	SOFFISOF BRIEFS AIR DRY MAXI PLUS SIZE XXLARGE 4X15 PCS
01115.U	SOFFISOF BRIEFS AIR DRY EXTRA SIZE SMALL 6X15 PCS
01116.U	SOFFISOF BRIEFS AIR DRY EXTRA SIZE MEDIUM 6X15 PCS
01117.U	SOFFISOF BRIEFS AIR DRY EXTRA SIZE LARGE 6X15 PCS
01118.U	SOFFISOF BRIEFS AIR DRY SUPER SIZE MEDIUM 6X15 PCS
01034.U	SOFFISOF BRIEFS AIR DRY SUPER PLUS SIZE MEDIUM 6X15 PCS
01119.U	SOFFISOF BRIEFS AIR DRY SUPER SIZE LARGE 6X15 PCS
01035.U	SOFFISOF BRIEFS AIR DRY SUPER PLUS SIZE LARGE 6X15 PCS
01120.U	SOFFISOF BRIEFS AIR DRY SUPER SIZE XLARGE 4X15 PCS
01121.U	SOFFISOF BRIEFS AIR DRY MAXI SIZE MEDIUM 4X15 PCS
01036.U	SOFFISOF BRIEFS AIR DRY MAXI SUPER SIZE MEDIUM 4X15 PCS
01122.U	SOFFISOF BRIEFS AIR DRY MAXI SIZE LARGE 4X15 PCS
01037.U	SOFFISOF BRIEFS AIR DRY MAXI SUPER SIZE LARGE 4X15 PCS

Product Code	Description CLASSIC BRIEFS
01123.U	SOFFISOF BRIEFS AIR DRY MAXI SIZE XXLARGE 4X15 PCS
01124.U	SOFFISOF BRIEFS AIR DRY MAXI SIZE XXXLARGE 4X15 PCS
01125.U	SOFFISOF BRIEFS AIR DRY MAXI PLUS SIZE SMALL 6X15 PCS
01126.U	SOFFISOF BRIEFS AIR DRY MAXI PLUS SIZE MEDIUM 4X15 PCS
01127.U	SOFFISOF BRIEFS AIR DRY MAXI PLUS SIZE LARGE 4X15 PCS
01128.U	SOFFISOF BRIEFS AIR DRY MAXI PLUS SIZE XXLARGE 4X15 PCS
01102	SOFFISOF BRIEFS CLASSIC EXTRA SIZE MEDIUM 6X15 PCS
01103	SOFFISOF BRIEFS CLASSIC EXTRA SIZE LARGE 6X15 PCS
01105	SOFFISOF BRIEFS CLASSIC SUPER SIZE XLARGE 4X15 PCS
01106	SOFFISOF BRIEFS CLASSIC MAXI SIZE MEDIUM 4X15 PCS
01107	SOFFISOF BRIEFS CLASSIC MAXI SIZE LARGE 4X15 PCS
01108	SOFFISOF BRIEFS CLASSIC MAXI SIZE XXLARGE 4X15 PCS
00975	SOFFISOF CLASSIC BRIEFS SUPER SIZE MEDIUM 4X30 PCS
00976	SOFFISOF CLASSIC BRIEFS SUPER SIZE LARGE 4X30 PCS
01102.U	SOFFISOF BRIEFS CLASSIC EXTRA SIZE MEDIUM 6X15 PCS
01103.U	SOFFISOF BRIEFS CLASSIC EXTRA SIZE LARGE 6X15 PCS
01105.U	SOFFISOF BRIEFS CLASSIC SUPER SIZE XLARGE 4X15 PCS
01106.U	SOFFISOF BRIEFS CLASSIC MAXI SIZE MEDIUM 4X15 PCS
01107.U	SOFFISOF BRIEFS CLASSIC MAXI SIZE LARGE 4X15 PCS
01108.U	SOFFISOF BRIEFS CLASSIC MAXI SIZE XXLARGE 4X15 PCS
00975.U	SOFFISOF CLASSIC BRIEFS SUPER SIZE MEDIUM 4X30 PCS
00976.U	SOFFISOF CLASSIC BRIEFS SUPER SIZE LARGE 4X30 PCS

are identified with the basic UDI-DI code 8007300FAM0000007Z2, are in compliance with and satisfy all applicable provisions of EU Regulation 745/2017 (hereinafter referred to as MDR) and subsequent amendments and additions.

To this end, the undersigned guarantees and declares under its own responsibility that the above-mentioned medical devices:

- 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, to wear as a substitute for underwear
- not designed to be used together with other medical devices.

The medical device "BRIEFS", intended for adult incontinence, is designed for the absorption, retention and containment of urine leakages in adult users.

The product is designed to:

- Manage all types of incontinence, ranging from light to severe;
- Keep the skin dry;
- Ensure the user comfort;
- Be used in various care settings (e.g. home, long-term care facilities).

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), April 9th 2026

Signature

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Dott. Cesare Battaglia
CEO