

## ***EU Declaration of Conformity***

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### **DECLARES**

That the following Medical Devices:

| <b>Product Code</b> | <b>Description</b>                                 |
|---------------------|----------------------------------------------------|
| 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    |
| 02876               | SOFFISOF AIR DRY PANTS SUPER SIZE XXLARGE 4X10 PCS |
| 00912.U             | SOFFISOF AIR DRY PANTS EXTRA SIZE SMALL 6X14 PCS   |
| 02858.U             | SOFFISOF AIR DRY PANTS PLUS SIZE MEDIUM 6X14 PCS   |
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| 02869.U             | SOFFISOF AIR DRY PANTS EXTRA SIZE LARGE 4X8 PCS    |
| 02872.U             | SOFFISOF AIR DRY PANTS EXTRA SIZE XLARGE 4X12 PCS  |
| 02873.U             | SOFFISOF AIR DRY PANTS SUPER SIZE XLARGE 4X8 PCS   |
| 02874.U             | SOFFISOF AIR DRY PANTS SUPER SIZE MEDIUM 4X9 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.

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), 27/03/2025*

Signature

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Dott. Cesare Battaglia

CEO