COREMEC
Hospital Supplies
Galeno

kiwa certified
CERMET
UNI EN ISO 9001:2015
SISTEMA DI GESTIONE CERTIFICATO

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DECLARATION OF CONFORMITY
ACCORDING TO REGULATION (EU) NO. 2017/745

Having taken note of Regulation (EU) no. 2017/745 regarding medical devices, its amendments and additions, COREMEC S.r.l. as the manufacturer declares, under its sole responsibility, that the devices identified as:

Basic UDI-DI: 805330753ATTARTBX

COD.	**Limb holder**
2100	Limb holder with velcro for adults
2100TM	Fast opening limb holder, for adults in medical TNT
2150	Paediatric limb holder with velcro
2200	Reinforced limb holder with ring
2200TM	Reinforced limb holder with ring, in medical TNT
2300	Limb holder with protective mitt
2350	Limb holder with protective mitt - ICU model

Intended use: aid designed to limit and control the movements of patients in a state of confusion. To be applied to the upper (wrist) and/or lower (ankle) limbs.

falling within class I, they are marked CE meeting the required requirements and being in possession of the related technical documentation referred to in Annex II of Regulation (EU) no. 2017/745.

The products covered by this declaration also comply with the following regulations:

- UNI CEI EN ISO 14971 – Application of risk management to medical devices
- UNI CEI EN ISO 15223-1 – Medical devices - Symbols to be used with information to be supplied by the manufacturer

Nichelino, lì 23 November 2022

*Mrs. Oriana Ponzuoli *** Coremec s.r.l. * Legal Representative * General Manager*

Digitally signed by Şarco Alexandru
Date: 2022.11.24 14:47:43 EET
Reason: MoldSign Signature
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COREMEC

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Rating di Legalità ★★
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