DECLARATION OF CONFORMITY

EU Representative

CMC MEDICAL DEVICES & DRUGS S.L.
C/ Horacio Lengo Nº 18, CP 29006,
Málaga, Spain.
SRN: NL-AR-000000293

Manufacturer

THIS DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE LEGAL MANUFACTURER:

Name: YASCO
Address: No.179-52 & No.179-53, Da Kang Lang, Daxiang Village, Pu Zi City, Chia Yi County 613, Taiwan.
SRN: TW-MF-000009946

Conformity Assessment

Are class I medical devices as defined in the Annex VIII of the Regulation (EU) 2017/745

ARE IN CONFORMITY WITH THE REQUIREMENTS OF REGULATION (EU) 2017/745 ANNEX I RELATING TO CLASS I MEDICAL DEVICES

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document .

Date de marquage CE - CE marking date : 2023.01.16

Version du dossier technique de marquage CE - CE marking technical file version :CE-MDR-TCF001

Product Information

Name: COMFORT/HOOK-AND LOOP STRAP 40CM
Model: 856001
GMDN: 58964
Basic UDI-DI: 47165681017264E
Classification: Class I
Intended use: Strap for leg bag
EMDN: A06030399

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

YASCO ENTERPRISE CORP YASCO

Signature:

Date: July 18, 2025

Jack Wu

Position: **General manager**

Place: TAIWAN