

Declaration of Conformity

We, First Care Products Ltd., hereby declare on our own responsibility that the distributed CE marked products, specified in the annex product list, meets the provisions of the Council Directive 93/42/EEC of June 1993, as amended by Directive 2007/47/EC, which apply to the products. Conformity assessment was performed according to Annex II.

The conformity with the essential requirements set out in Annex I of the 93/42/EEC Directive has been demonstrated against the following harmonized standards: EN ISO 13485:2016, EN ISO 14971:2012, EN 62366-1:2015, EN ISO 10993-1:2009/AC:2010, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11737-2:2006, EN ISO 11607-1:2017, EN ISO 11607-2:2017, EN 1041:2008+A1:2013 and EN ISO 15223-1:2016.

The product(s) are covered by the "EC Certificate", reference number **ECM20MDD014 rev.1** delivered by **ENTE CERTIFICAZIONE MACCHINE SRL** (Via Ca' Bella, 243/A - loc. Castello di Serravalle, 40053 Valsamoggia, Italy) Notified Body Identification Number: 1282.

<u>Manufacturer</u>	First Care Products, Ltd. 10 Amal St. Afek Industrial Park, Rosh Ha'Ayin. Zip 4809234, Israel.
<u>EU Authorized Representative</u>	MedNet EC-REP GmbH Borkstraße 10, 48163 Münster, Germany

Place: Rosh-Ha'Ayin, Israel

Date: October 20, 2020

Signature: 
Roee Madai,
CEO, First Care Products

מנכ"ס רישוי בע"מ
First Care Products, Ltd.

The PerSys Medical Group



Annex - Product List

Products Class: Is

MDD Annex IX Rule: 4

Device Category: Sterile Bandage used for emergency care

GMDN Code: 47011

List of Products	REF (xxxxx=define feature and distributor/language)
Emergency Bandages Line	
FCP01 - 4" Emergency Bandage	1001xxxxx
FCP02 - 6" Emergency Bandage	1002xxxxx
FCP03 - 4" Emergency Bandage	1003xxxxx
FCP05 - 6" Emergency Bandage w/2nd Mobile Pad	1005xxxxx
FCP06 - 6" Emergency Bandage	1006xxxxx
FCP07 - 4" Emergency Bandage w/2nd Mobile Pad	1007xxxxx
FCP09 - 8" Abdominal Emergency Bandage	1009xxxxx
FCP10 - 8" Abdominal Emergency Bandage	1010xxxxx
FCP11 - 4" Emergency Bandage w/2nd Mobile Pad	1011xxxxx
FCP12 - 6" Emergency Bandage w/2nd Mobile Pad	1012xxxxx
T3 - Tactical Trauma Treatment	1054xxxxx /1055xxxxx
T6 - Tactical Trauma Treatment	1057xxxxx/1058xxxxx
Medical Gauze (4" and 6")	1020xxxxx
Multi Bandages Line	
FCP09+ Multi Bandage	1009x9xxx
FCP10+ Multi Bandage	1010x9xxx
FCP19 - 4" Tactical Multi Bandage	1019xxxxx
FCP29 - 6" Tactical Multi Bandage	1029xxxxx
FCP09T - 8" Tactical Multi Bandage	1059xxxxx
FCP10T - 8" Tactical Multi Bandage	1069xxxxx
Wound Stop Bandages Line	
WoundStop HomeCare	1040xxxxx
WoundStop Care1 - 4"	1041xxxxx
WoundStop Care1+ - 6"	1042xxxxx

The PerSys Medical Group

