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.

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

Place: Rosh-Ha'Ayin, Israel

Date: October 20, 2020

Signature:

מוצרי פירסט קיירס בע"מ
First Care Products, Ltd.

Roee Madai,
CEO, First Care Products

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

Ente Certificazione Macchine

Notified Body n. 1282 - Testing Laboratory – Nr. 121697 PJLA
Authorized Training Body n. 6737 - Inspection Body

CONFIRMATION LETTER IN THE FRAMEWORK OF REGULATION EU 2023/607

FOR "LEGACY" DEVICES ACCORDING TO DIRECTIVE 93/42/EEC

REFERENCE N° 36/F

ENTE CERTIFICAZIONE MACCHINE SRL
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) – Italy
☎ 051.6705141 🖷 051.6705156 ✉ info@entecerma.it www.entecerma.it

ENTE CERTIFICAZIONE MACCHINE

First Care Products Ltd.

Single Registration Number: IL-MF-000018897
Address: 10 Amal St., Industrial Street Park, Rosh Ha'Ayin, Central, Israel
Referent: Mr. Haim Bedani

CONFIRMATION LETTER IN THE FRAMEWORK OF REGULATION EU 2023/607

FOR "LEGACY" DEVICES
ACCORDING TO DIRECTIVE 93/42/EEC

Confirmation of the status of a formal application, written agreement, and appropriate surveillance activity in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Ente Certificazione Macchine srl (ECM), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **1282 on NANDO**, confirms to have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and to have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with **First Care Products Ltd**.

In addition, this letter confirms that **ECM**, where relevant, has signed a written agreement **First Care Products Ltd**. governing transfer of the surveillance activitiy in accordance with Article 120, paragraph 3e of MDR as amended by Regulation (EU) 2023/607.

The devices covered by the formal application and the written agreements mentioned above are identified in the Tables below. **Table 1** identifies devices for which an MDR application has been received, written agreement concluded, and for which **ECM** is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. **Table 2** identifies devices for which an MDR application has been received and a written agreement concluded, but **ECM** has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR repectively, by 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3 of MDR (as amended by EU 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

ENTE CERTIFICAZIONE MACCHINE SRL
LUCA BEDONNI

Table 1 Devices covered by this letter and for which ECM is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application
Sterile Bandages and Medical Gauzes	☐ Class IIb device ☐ Class IIa device ☒ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☐ MDD/AIMDD device identification: ☒ Not applicable	☒ MDD/AIMDD Certificate ECM20MDD014 rev.1 issued by Ente Certificazione Macchine srl, NB number 1282 ☐ Not applicable

Tabella 2 Dispositivi oggetto della presente lettera e per i quali ECM NON è responsabile dell'adeguata sorveglianza ai sensi della Direttiva applicabile: N.A.