



n. **ECM20MDD014 rev.1**

Data di prima emissione * <i>Date of first issue</i>	17/10/2017
Data di emissione <i>Date of issue</i>	22/09/2020
Data di ultimo rinnovo <i>Date of last renewal</i>	22/09/2020
Data di revisione <i>Date of revision</i>	06/10/2020
Data di scadenza <i>Expiry date</i>	27/05/2024

Certificato CE

EC Certificate

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)
Issued according to 93/42/EEC directive – Annex II (excl. clause 4)

Richiedente

Applicant

Ragione Sociale

First Care Products, Ltd.

Company Name

Sede legale

10 Amal St. Afek Industrial Park,

Legal address

Località

Rosh Ha'Ayin, 4809234 Israel

Place

Sito produttivo

40 Abu Yosif, Kfar Tuba-Zangaryye, 12310 Israel

Place of production

14 Amal St. Afek Ind. Park, 4809234, Rosh Ha'Ayin, Israel

Dispositivo Medico

Bandages for wound care and pneumatic tourniquet

Medical device

Identificato come

Vedi allegato al presente certificato

Identified as

See the annex of this certificate

ECM, Organismo Notificato n° 1282 ha verificato il Sistema Qualità in accordo all'allegato II (escluso punto 4) della direttiva 93/42/CEE e ha rilevato che ne soddisfa i requisiti.

Si fa riferimento al rapporto di audit di emissione del presente certificato del 10 luglio 2020; rif. piano di certificazione: FirstCare-19.06

ECM, Notified Body n° 1282 has verified the Quality System in accordance with annex II (excluding clause 4) of the 93/42/EEC directive and found that it meets aforesaid requirements.

Reference to the audit report related to issue of the present certificate dated 10th July 2020; ref. certification plan: FirstCare-19.06

Firma autorizzata

Authorized signature

(Federica Secchi – Technical Director)

*certificato rilasciato per la prima volta da altro Organismo di Certificazione
certificate issued for the first time by another Certification Body

Questo certificato, compreso l'allegato (se presente), può essere riprodotto solo integralmente e senza alcuna variazione
This certificate, annex included (where applicable), may only be reproduced in its entirety and without any change

Ente Certificazione Macchine srl

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Allegato al Certificato CE

Annex to EC Certificate

Rilasciato i sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)
Issued according to 93/42/EEC directive – Annex II (excl. clause 4)

Elenco dei Dispositivi Medici inclusi in questo certificato List of Medical Devices included in this certificate

Descrizione Description	Classe di rischio Risk class	Codice NBOG NBOG code	Modello Model	Taglie Sizes
FCP01 - 4" Emergency Bandage	Is	MD0301 MDS7006	FCP01	N.A.
FCP02 - 6" Emergency Bandage	Is	MD0301 MDS7006	FCP02	
FCP03 - 4" Emergency Bandage	Is	MD0301 MDS7006	FCP03	
FCP05 - 6" Emergency Bandage w/2nd Mobile Pad	Is	MD0301 MDS7006	FCP05	
FCP06 - 6" Emergency Bandage	Is	MD0301 MDS7006	FCP06	
FCP07 - 4" Emergency Bandage w/2nd Mobile Pad	Is	MD0301 MDS7006	FCP07	
FCP09 - 8" Abdominal Emergency Bandage	Is	MD0301 MDS7006	FCP09	
FCP10 - 8" Abdominal Emergency Bandage	Is	MD0301 MDS7006	FCP10	
FCP11 - 4" Emergency Bandage w/2nd Mobile Pad	Is	MD0301 MDS7006	FCP11	
FCP12 - 6" Emergency Bandage w/2nd Mobile Pad	Is	MD0301 MDS7006	FCP12	
T3 - Tactical Trauma Treatment	Is	MD0301 MDS7006	T3	
T6 - Tactical Trauma Treatment	Is	MD0301 MDS7006	T6	
Medical Gauze (4" and 6")	Is	MD0301 MDS7006	Medical Gauze	4" and 6"
FCP09+ Multi Bandage	Is	MD0301 MDS7006	FCP09+	
FCP10+ Multi Bandage	Is	MD0301 MDS7006	FCP10+	
FCP19 - 4" Tactical Multi Bandage	Is	MD0301 MDS7006	FCP19	
FCP29 - 6" Tactical Multi Bandage	Is	MD0301 MDS7006	FCP29	
FCP09T - 8" Tactical Multi Bandage	Is	MD0301 MDS7006	FCP09T	

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FCP10T - 8" Tactical Multi Bandage	Is	MD0301 MDS7006	FCP10T	
WoundStop HomeCare	Is	MD0301 MDS7006	WoundStop HomeCare	
WoundStop Care1 - 4"	Is	MD0301 MDS7006	WoundStop Care1	
WoundStop Care1+ - 6	Is	MD0301 MDS7006	WoundStop Care1+	
Pneumatic Tourniquet	Ila	MD1103	Quick-T Tourniquet	

Firma autorizzata
Authorized signature

(Federica Secchi – Technical Director)

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