



EC Certificate Production Quality Assurance

Certificate No.: EU1009413

Date: 2015-09-28

Order No.: 136524

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 1690 of 15th December 2005 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Manufacturer:	First Care Products, Ltd. 10 Amal St. Afek Industrial Park, Rosh Ha'Ayin. P.O.B. 11790, Zip 4809234 Israel
Device categorie(s):	MD0301
GMDN code:	See page two
Models:	See page two
Risk class as defined by the manufacturer:	Is
Standards/provisions:	The audit of the quality system was based upon and assessed according to the provisions in Annex V of the EC-Directive 93/42/EEC.
Date of audit:	2015-03-09
End of the validity:	2020-10-01
Nemko EC notification No.:	0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled by the manufacturer and the factory. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC.

Ragnar Stranger Christiansen
For Nemko AS





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Certificate History:

Revision	Description	Issue Date
0.0	Initial certification	2010-09-27
1.0	Update of certificate	2012-05-24
2.0	Re-certification	2015-09-22
3.0	Added device	2015-09-28

The certificate referred to above, includes the following devices/models:

Device Category	Model Name	GMDN Code
MD0301, First aid gauze / bandage	FCP01 - 4" Emergency Bandage Green	47011
	FCP02 - 6" Emergency Bandage Green	47011
	FCP03 - 4" Emergency Bandage White	47011
	FCP05 - 6" Emergency Bandage w/2nd Mobile Pad Green	47011
	FCP06 - 6" Emergency Bandage White	47011
	FCP07 - 4" Emergency Bandage w/2nd Mobile Pad Green	47011
	FCP09 - 8" Abdominal Emergency Bandage Green	47011
	FCP10 - 8" Abdominal Emergency Bandage White	47011
	FCP11 - 4" Emergency Bandage w/2nd Mobile Pad White	47011
	FCP12 - 6" Emergency Bandage w/2nd Mobile Pad White	47011
	FCP09+ Multi Bandage Green	47011
	FCP10+ Multi Bandage White	47011
	WoundStop - First Aid Wound Dressing Off-White	47011
	WoundStop PRO 4" Trauma Dressing Off-White	47011
	WoundStop PRO+ 6" Trauma Dressing Off-White	47011
	WoundStop HomeCare White	47011
	WoundStop Care1 - 4" White	47011
	WoundStop Care1+ - 6" White	47011
	FCP19-4" Tactical Multi Bandage	47011
	FCP29-6" Tactical Multi Bandage	47011
	FCP09T-8" Tactical Multi Bandage	47011
	T3- Tactical Trauma Treatment	47011

