

Bfactory Health Products B.V.

Remmerden 58
3911 TZ Rhenen
The Netherlands

DECLARATION OF CONFORMITY

medical devices

We hereby declare that the CE marked Class IIa and Class IIb medical devices, specified in the annexed product list, are covered by the "CE Marking of Conformity Certificate", reference number: 2036399CE02, issued on 28 January 2014 delivered by DEKRA Certification B.V., Arnhem, The Netherlands, Notified Body Identification Number 0344, and conform to the quality system and technical documentation requirements in accordance with Annex II of the "EC-Directive", the Council Directive 93/42/EEC of 14 June 1993, concerning Class IIa and Class IIb medical devices.

This declaration is supported by the Quality Management System certification based on the harmonized standards EN ISO 13485:2016, Quality System Certificate with reference number: 2166303, issued on 19 December 2014 and issued by DEKRA Certification B.V.

This Declaration of Conformity covers the product as listed in Annex 1 to this Declaration and is valid for all products concerned bearing the CE marking.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Bfactory Health Products B.V.

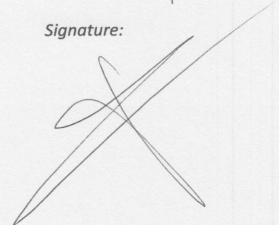
*Remmerden 58
3911 TZ Rhenen
The Netherlands*

Represented by:

*Name: Tineke Creemers-Molenaar
Function: Director & RA Manager*

Date: 2-7-2024

Signature:

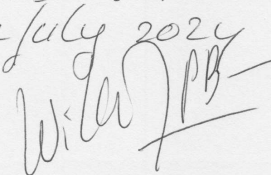


Name: Willem Jan Bosma

Function: Director & Manager Representative

Date: 2 July 2024

Signature:





FRM731-10.16

Annex 1: List of Products

<i>Product naam</i>	<i>Basic UDI-DI</i>	<i>Internal Product admin code</i>	<i>Registration Class</i>	<i>First batch</i>	<i>Last batch</i>
Revamil Balm / Baume	08717438CreamBased8X	10500 / 10550 (15 g)	Ila	8HD15 / 4FD5 XT	See FRM824-12 Batchlijst
Anamel sachet individual 2gr	08717438CreamBased8X	20821	Ila	DCM	
Dermel sachet individual 2gr	08717438CreamBased8X	20266	Ila	DCN	
Nasumel sachet individual 2gr	08717438CreamBased8X	20306	Ila	DCP	
Dermagiq Wound sachet individual 2gr	08717438CreamBased8X	20406	Ila	DCK	See FRM824-12 Batchlijst
Dermagiq Skin sachet individual 2gr	08717438CreamBased8X	20466	Ila	DCL	
Revamil Balm / Baume Sachets 2gr Individual	08717438CreamBased8X	10504	Ila	213D5-1	
Revamil Balm / Baume Sachets per 10 2gr	08717438CreamBased8X	10506	Ila	18110/E	
Dermel 50 gr	08717438CreamBased8X	20202	Ila	09A13/E2	See FRM824-12 Batchlijst
Dermel 15 gr	08717438CreamBased8X	20650	Ila	ONLA5	
Nasumel heuszaif 15gr	08717438CreamBased8X	20300	Ila	8FM15	See FRM824-12 Batchlijst
Anamel 15gr	08717438CreamBased8X	20800	Ila	9GN15	
STB wound dressing 15gr	08717438CreamBased8X	30180	Ila	OKR15	
Dermagiq Skin 30gr	08717438CreamBased8X	20700	Ila	9CK30	
Dermagiq Skin 50gr	08717438CreamBased8X	20731	Ila	KE	
Dermagiq Proct 15gr	08717438CreamBased8X	20750	Ila	OMP5	
Dermagiq Wound 15gr	08717438CreamBased8X	20790	Ila	J9	
Revamil 5 gr	08717438PureHoneyST	10010	Ilb	3LA5	
Revamil 18 gr	08717438PureHoneyST	10100	Ilb	8HA18	
Revamil 18 gr Miel	08717438PureHoneyST	10102	Ilb	ZJ	
Revamil Single Dose	08717438PureHoneyST	10200	Ilb	8MB02	
Revamil Wound Dressing 8x8 per 7	08717438PureHoneyST	10300	Ilb	8FG8	
Revamil Tulle 8x8 per 5	08717438PureHoneyST	10318	Ilb	XP	
Revamil Wound Dressing 5x5 per 10	08717438PureHoneyST	10307	Ilb	0IG5	
Revamil Tulle 5x5 per 5	08717438PureHoneyST	10304	Ilb	E9	
Revamil Wound Dressing 10x20	08717438PureHoneyST	10305	Ilb	9NG20	
Revamil Wound Dressing 10x10	08717438PureHoneyST	10302	Ilb	3BG20	



FRM731-10.16

Product naam

Basic UDI-DI

Internal Product
admin code

Registration
Class

First batch

Last batch

Revamil Melghinate 5x5	08717438PureHoneyST	10380	IIb	5DAG5	
Revamil Melghinate 10x10	08717438PureHoneyST	10350	IIb	3EMG10	
Dermel Wound Dressing 8x8, per 12	08717438PureHoneyST	10400	IIb	9NM8	

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