Declaration of conformity

Identification of the Legal Manufacturer:	SRN BE-M-000000258 Flen Health NV, located at Blauwesteenstraat 87, 2550 Kontich, Belgium
Manufacturing outsourced to	• Conforma NV located at Zenderstraat 10, 9070 Destelbergen, Belgium

This Declaration of Conformity is issued under the sole responsibility of **Flen Health NV.**

Identification of the device(s) concerned:

Flaminal® Forte or FlamiZorb® Forte. Basic-UDI: 5420013FlaminalForte01KK

Intended Purpose: Primary wound care product for acute and chronic wounds and irritated skin: intended for moderately to highly exuding wounds.

Flaminal® Hydro or FlamiZorb® Hydro. Basic-UDI: 5420013FlaminalHydro01LZ

Intended Purpose: Primary wound care product for acute and chronic wounds and irritated skin: intended for slightly to moderately exuding wounds.

Both products are: Alginate dressings M040402 and manufactured under a quality certificate for standard ISO 13485:2016, with number 2071633, approved by Dekra Certification B.V., Notified Body 0344.

Product list

Trade name : Flaminal® Forte - Other name: FlamiZorb® Forte
First batch: V27683 – manufacturing date 08/June/2023
Last batch:

Trade name :	Packsize	Ref Nr	Trade name	Packsize	Ref Nr
Flaminal® Forte	10 g	1017	FlamiZorb® Forte	10 g	1053
Flaminal® Forte	15 g	1012	FlamiZorb® Forte	15 g	1069
Flaminal® Forte	25 g	1033	FlamiZorb® Forte	25 g	1070
Flaminal® Forte	30 g	1018	FlamiZorb® Forte	30 g	1071
Flaminal® Forte	40 g	1034	FlamiZorb® Forte	40 g	1072
Flaminal® Forte	50 g	1015	FlamiZorb® Forte	50 g	1054
Flaminal® Forte	5x15 g	1012	FlamiZorb® Forte	500 g	1073
Flaminal® Forte	10x10 g	1017	FlamiZorb® Forte	5x15 g	1074
Flaminal® Forte	500 g	1016			

Trade Name : Flaminal® Hydro - Other name: FlamiZorb® Hydro
First batch: V27820 manufacturing date 15/June/2023
Last batch:

Trade name :	Packsize	Ref Nr	Trade name	Packsize	Ref Nr
Flaminal® Hydro	10 g	1008	FlamiZorb® Hydro	10 g	1051
Flaminal® Hydro	15 g	1013	FlamiZorb® Hydro	15 g	1063
Flaminal® Hydro	25 g	1031	FlamiZorb® Hydro	25 g	1064
Flaminal® Hydro	30 g	1009	FlamiZorb® Hydro	30 g	1065
Flaminal® Hydro	40 g	1032	FlamiZorb® Hydro	40 g	1066
Flaminal® Hydro	50 g	1021	FlamiZorb® Hydro	50 g	1052
Flaminal® Hydro	5x15 g	1013	FlamiZorb® Hydro	500 g	1068
Flaminal® Hydro	10x10 g	1008	FlamiZorb® Hydro	5x15 g	1067
Flaminal® Hydro	500 g	1010			

Risk Classification:	Non-invasive medical device of class IIb according to rule 4 of annex VIII of the Medical Device Regulation 2017/745 Products are in class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent,

- We hereby declare that the above-mentioned devices comply with the European Medical Device Regulation 2017/745 especially:
- The obligation to establish a technical documentation file for our new product family, as required by Annex II and Annex III of the Medical Device Regulation 2017/745 and keep this technical documentation file available for the competent authorities;
- That our labelling and instructions for use respect the requirements of the Medical Device Regulation 2017/745.

To have a vigilance system and traceability in place.

Relevant (Harmonized) Standards	EN ISO 10993-1 EN ISO 10993-3 EN ISO 10993-5 EN ISO 10993-10 EN ISO 10993-11	EN ISO 10993-12 EN ISO 10993-23 EN ISO 13485 EN 13726-1 EN ISO 14155	EN ISO 15223-1 EN ISO 15223-2 IEC 62366 ISO TR 20416 EN ISO 14971 EN ISO 20417
Name and address of Notified Body	Notified Body 0344: Dekra Certification B.V. – Meander 1061, 6825 MJ Arnhem, The Netherlands		
Applicable CE Certificate(s):	EC quality certificate **2253359CE01** , delivered by Dekra Certification B.V, accordance with annex IX chapter II & III of the Medical Device Regulation 2017/745		
Initial date of certification	28 November 2022		
Identification of the person authorized to sign on behalf of Flen Health NV:	Accordingly, as the Person Responsible for Regulatory compliances for Flen Health NV, I approve the placing of the CE mark on all products until significant changes are made to the product, its starting materials or key subcontractors. Name: Philippe Sollie Signature: _____ Title: Executive Chairman Place of Issue: Kontich, Belgium Date: 19 APRIL 2024 Flen Health NV Blauwesteenstraat 87 B-2550 Kontich (Antwerp) Belgium Tel: +323 825 70 63 Fax: +323 226 46 58 VAT BE 0473 295 959		