

Declaration of Conformity

Polymeric Resins for dental prostheses, pain release, splints and dental prostheses retainers

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Polymeric Resins for dental prostheses, pain release, splints and dental prostheses retainers
Legal Manufacturer: (Name on Label)	FLEXAFIL SACI Leopoldo Marechal 1308 Ciudad Autonoma De Buenos Aires C1414BYE Argentina
Manufacturers SRN:	Not Yet Available
Basic UDI-DI:	30522838442INYECTABLESF2
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	The different polymeric resins are used to produce partial and full dentures, temporary crowns and bridges, clasps, attachment, telescopic work and for splints.
MDR Classification:	Class I – Rule V
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name Gad Cohen

Position

General Manager

Signed

Date

11/12/24

Place

Buenos Aires

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer

Appendix II – Product Listing/Schedule

Catalogue Number / UDI-DI	Device Name	EMDN Code
INJECTABLES	Polymeric Resins for dental prostheses, pain release, splints and dental prostheses retainers	Q010699
7798399351997	Thermoforming Sabilex sheets P211/60 and Thermoformer	Q010699
7798399351980	Resin Sabilex PremiumFlex GEN1 IPFGEN1	Q010699
7798399351973	Empty Cartridge	Q010699
7798399351966	Microinjectora Sabilex	Q010699
7798399351959	Resin Sabilex FlexiAcetal GEN1 IFAGEN1	Q010699
7798399351942	Resin Sabilex FlexiAcryl GEN2 IAFGEN2	Q010699
7798399351935	Resin Sabilex FlexiAcryl GEN1 IAFGEN1	Q010699
7798399351928	Resin Sabilex FlexiUltra GEN2 IFUGEN2	Q010699
7798399351911	Resin Sabilex FlexiUltra GEN1 IFUGEN1	Q010699
7798399351904	Resin Sabilex FlexiFast GEN2 IFFGEN2	Q010699
7798399351898	Resin Sabilex FlexiFast GEN1 IFFGEN1	Q010699
7798399351881	Resin Sabilex PremiumFlex 245 50 IPF24550	Q010699
7798399351874	Resin Sabilex PremiumFlex 245 XL D 25 IPF245XL25	Q010699
7798399351867	Resin Sabilex PremiumFlex 245 XL D 22 IPF245XL22	Q010699
7798399351850	Resin Sabilex PremiumFlex 245 L D 25 IPF245L25	Q010699
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7798399351836	Resin Sabilex PremiumFlex 245 M D 25 IPF245M25	Q010699
7798399351829	Resin Sabilex PremiumFlex 245 M D 22 IPF245M22	Q010699
7798399351812	Resin Sabilex PremiumFlex 245 S D 25 IPF245S25	Q010699
7798399351805	Resin Sabilex PremiumFlex 245 S D 22 IPF245S22	Q010699
7798399351799	Resin Sabilex PremiumFlex 238 50 IPF23850	Q010699
7798399351782	Resin Sabilex PremiumFlex 238 XL D 25 IPF238XL25	Q010699
7798399351775	Resin Sabilex PremiumFlex 238 XL D 22 IPF238XL22	Q010699
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7798399351737	Resin Sabilex PremiumFlex 238 M D 22 IPF238M22	Q010699

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7798399351713	Resin Sabilex PremiumFlex 238 S D 22 IPF238S22	Q010699
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7798399351690	Resin Sabilex BioStrong CW L D 25 IBSCWL25	Q010699
7798399351683	Lubricante Alta Temperatura I560	Q010699
7798399351676	Resin Sabilex BioStrong CW M D 25 IBSCWM25	Q010699
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7798399351638	Resin Sabilex BioStrong C 50 IBSC50	Q010699
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7798399350037	Resin Sabilex FlexiFast 100 50 IFF10050	Q010699
7798399350020	Resin Sabilex FlexiFast 100 L D 25 IFF100L25	Q010699
7798399350013	Resin Sabilex FlexiFast 100 M D 25 IFF100M25	Q010699

Version History

Version	Compiled by	Date	Description
1.0	G2d Cohen	6/10/22	First Issue
1.2	G2d Cohen	11/12/24	Added Item Empty Cartridge