Leopoldo Marechal 1312 - (CP1414) - Ciudad Autónoma de Buenos Aires – info@sabilex.com – www.sabilex.com

EC Declaration of Conformity

We, **FLEXAFIL SACI** located in **Ciudad Autónoma de Buenos Aires, Argentina**, manufacturers of **Deontological Products** as detailed hereunder, that are placed in the European market, declare that our products conform and meet the essential requirements set out in Annex I of the Medical Device Directive 93/42 EEC, and we have completed all requirement as set up in Annex VII.

#	Product	CLASS
1	**Polymeric Resins for Dental Prostheses, pain release splints and dental prostheses retainers**	I

Within those requirements we prepared the required technical documentation, put into place corrective action and vigilance procedures and have appointed Medes Limited from, 5 Beaumont Gate, Shenley Hill, Radlett Hearts, London WD7 7AR England, to act as our Authorized Representative in the European Community.

Signature: 

Name: Ricardo T. Falk

Position: President

Date: 27.03.2013

TRADE NAME: FLEXI FAST – FLEXI ULTRA

1- Identification of substance:

- Product details:
- Trade name: FLEXI FAST – FLEXI ULTRA
- Article number: HF-10 - HU10
- Application of the substance / the preparation Plastics processing industry
- Manufacturer/Supplier:
  FLEXAFIL S.A.C.I. LEOPOLDO MARECHAL 1312 – BUENOS AIRES – ARGENTINA
  TEL/FAX: 54-11-4854-4814 info@sabilex.com
- Emergency information:
  FLEXAFIL S.A.C.I. LEOPOLDO MARECHAL 1312 – BUENOS AIRES – ARGENTINA
  TEL/FAX: 54-11-4854-4814 info@sabilex.com

2- Composition/Data on components:

- Chemical characterization
- Description: Polyamide
- Dangerous components: Void
- Additional information For the wording of the listed risk phrases refer to section 16.

3- Hazards identification

§ Hazard designation: Void
§ Information pertaining to particular dangers for man and environment : The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

4- First aid measures

- General information No special measures required.
- After inhalation Seek medical treatment in case of complaints.
- After skin contact The product is not skin irritating.
- After eye contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult doctor.
- After swallowing In case of persistent symptoms consult doctor.

5- Fire fighting measures

§ Suitable extinguishing agents: CO2, extinguishing powder or water j et. Fight larger fires with water j et or alcohol-resistant foam.
§ Special hazards caused by the material, its products of combustion or flue gases:
Can be released in case of fire:
Carbon monoxide (CO)
Hydrogen cyanide (HCN)

§ Protective equipment: No special measures required.

6- Accidental release measures

- Person-related safety precautions: Not required.
- Measures for environmental protection: No special measures required.
- Measures for cleaning/collecting: Collect mechanically.
- Additional information: No dangerous materials are released.

7- Handling and storage

- Handling
  Information for safe handling: No special measures required.
  Information about protection against explosions and fires: No special measures required.

- Storage
  Requirements to be met by storerooms and containers: No special requirements.
  Information about storage in one common storage facility: Not required.
  Further information about storage conditions: None.

8- Exposure controls and personal protection

§ Additional information about design of technical systems: No further data; see item 7.
§ Components with critical values that require monitoring at the workplace:
§ The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

§ Personal protective equipment
§ General protective and hygienic measures: The usual precautionary measures should be adhered to in handling the chemicals.
§ Breathing equipment: Not required.
§ Protection of hands: Protective gloves.
§ Material of gloves: The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
§ Penetration time of glove material: The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed.
§ Eye protection: Safety glasses

9- Physical and chemical properties:

§ General Information

Form:	Granulate
Colour:	According to product specification
Smell:	Nearly odourless

§ Change in condition
Melting point/Melting range: 175-180°C
Boiling point/Boiling range: Not determined

§ Flash point: Not applicable

- Self-inflammability: Product is not selfigniting.
- Danger of explosion: Product is not explosive.
- Density at 20°C > 1 g/cm3

- Solubility in / Miscibility with
Water: Insoluble

10- Stability and reactivity

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- Dangerous reactions No dangerous reactions known
- Dangerous products of decomposition: No dangerous decomposition products known

11- Toxicological information

- Acute toxicity:
- Primary irritant effect:
on the skin: No irritant effect.
on the eye: No irritant effect.
- Sensitization: No sensitizing effect known.
- Additional toxicological information:
- When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

12- Ecological information:

- General notes: Generally not hazardous for water.

13- Disposal considerations

- Product:
- Recommendation : On the basis of the necessary technical regulations and after consultation with the disposal agent and the relevant authorities, can be deposited with

domestic waste or incinerated with domestic waste.

European waste catalogue
07 02 13 waste plastic

- Uncleaned packagings:
- Recommendation: Disposal must be made according to official regulations.

14- Transport information

- Transport/Additional information:
  Not dangerous according to the above specifications.
  (ADR/RID/IMDG/IATA)

15- Regulatory information

- Designation according to EC guidelines:
  The product is not subj ect to identification regulations under EC Directives.
- National regulations
- Water hazard class: Generally not hazardous for water.

16- Other information:

The information contained herein is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Department issuing data specification sheet: Environment and safety department

Contact:
Ricardo Falk
Tel.+54-11-4854-4814 info@sabilex.com

- 1 APR 2008

Safeguarding public health

MHRA

Our Ref: CA 010304

Benny Arazy
Medes Ltd
5 Beaumont Gate
Shenley Hill
Radlett
Herts
WD7 7AR
United Kingdom

31 March 2008

Dear Benny Arazy,

MEDICAL DEVICES REGULATIONS 2002: REGULATION 19
Registration of Persons Placing General Medical Devices on the Market

Thank you for informing the Competent Authority of the details of ***Manufacturers*** **Name:- Flexafil S.A.C.I)** located at **Manufacturers Address:- Lopoldo Maechal 1312 - 1414 Bueon Aires Argentina** for whom you are acting as the authorised representative and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "medical device", and that you have classified it/them as falling within Regulation 19 taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG2 form and means that:

For Manufacturers of Class I medical devices, Assemblers, and Sterilisers

You should now be operating under the Medical Devices Directive and the above Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

For Manufacturers of Custom-made devices

You should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any changes to:

- the company information
- additional generic groups of devices (not individual products within an existing generic group)
- discontinuation of a generic group of devices.

Please use RG2, the Registration form, to tell us about any of these changes.

Thank you for registering the following generic groups of devices:

Class I Devices:
Base Materials

Custom Made Devices:
None

Products Covered By Article 12:
None

Should you have any queries regarding your registration please do not hesitate in contacting us.

Yours sincerely

Dhruti Patel

Regulatory Affairs Administrator

Tel: 0207 084 3318

Fax: 0207 084 3107:

Email: dhruti.patel@mhra.gsi.gov.uk