EU DECLARATION OF CONFORMITY

Manufacturer : FDE

Adress : 46, rue du Zornhoff
67700 MONSWILLER

I, the undersigned, Raphaël VICO, ensure and declare that :

- The medical devices in Class IIb and IIa, listed below, meet the essential requirements of European Directive 93/42, the applicable harmonized standards and the applicable provisions under Title I of Book II of the French Code Public Health Part V.
- The medical devices are place on the market in accordance with the technical documentation referred to in point 3 of Annex II of Directive 93/42.
- The medical devices listed below are conform to the essential requirements and methods of conformity in point 3 of Annex II.
- The company is validated by the notified body GMED (n°0459), according to the Annex II excluding section 4, certificate number 32586.
- These medical devices also meet the requirements of :
    - European Directive 2011/65 on the limitation of the use of certain hazardous substances in electrical and electronic equipment.
    - The European Radio Equipment Directive 2014/53.
- These medical devices do not contain any phthalates, products of animal origin, products derived from human blood or medicinal substances.
- These medical devices are developed in France by FDE as manufacturer.
- The CE marking applies to the products listed below as of their first placement on the market.

Products	Reference	Date of 1rst placement on market
SO-CONNECT+ Ambulatory infusion pump Class IIb	SO-CONNECT+	17 June 2019
SO-FILL : sterile, single-use 20ml SO-CONNECT Syringe Class IIa	SO-FILL 20	27 February 2017
SO-FILL : sterile, single-use 30ml SO-CONNECT Syringe Class IIa	SO-FILL 30	27 February 2017
SO-FILL : sterile, single-use 50ml SO-CONNECT Syringe Class IIa	SO-FILL 50	27 February 2017

Date : 29/05/2019

Raphaël VICO
CEO