



EC DECLARATION OF CONFORMITY

Annex VII of European Directive 93/42/EEC

Freka-Clyss
(Product name)

See attached list
(Article number)

Class I
(Annex IX, rule 5)

We
Fresenius Kabi France
5 place du Marivel, 92316 Sèvres Cedex
France

On behalf of

Fresenius Kabi AG
D-61346 Bad Homburg
Germany

legal manufacturer of the above products, hereby declare under our sole responsibility for this Declaration of Conformity that the referenced products comply with all relevant provisions of Directive 93/42/EEC, as amended by 2007/47/EC, and its transposition into national laws. The products comply with the essential requirements of Annex I, further applicable standards and/or other normative documents as listed in the applicable technical documentation. All supporting documentation is kept under the premises of the manufacturer.

Sèvres 6th January 2021

Place and date of issue

S. BERTHOV-TALAB. Responsable Pharmacist

Name (printed letters), position and signature of authorized person

Valid starting with the original date of the document until product change

FREKA-CLYSS
(attachement to Declaration of Conformity regarding medical devices)

Article number	Product name	Product group
1992081	Freka-Clyss 120 mL (10 bags)	ENEMA
1993081	Freka-Clyss 120 mL (1 bag)	ENEMA