

## EC DECLARATION OF CONFORMITY

(Annex II.3 of Directive 93/42/EEC; according to EC-certificate No. G1 047402 0083 Rev. 00 and expiry date 26 May 2024, issued by notified body TÜV SÜD Product Service GmbH, Ridlerstrasse. 65, 80339 Munich, Germany, CE 0123)

Lavasorb

(Product name)

Refer to attachment (article number)

Class III

We Fresenius Kabi AG 61346 Bad Homburg, Germany

Manufacturer of the above products, hereby declare under our sole responsibility 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 1, 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, May 19<sup>th</sup>, 2021

Sylvie BERTHOU-TALAB Responsible Pharmacist

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



## **Attachment to EC Declaration of Conformity**

Article Code	Description	GMDN	Physical Manufacturer (name and address)
B231513	Lavasorb, 250 mL in Versylene container	37207	Fresenius Kabi France 6 rue du Rempart 27400 Louviers (France)
B231513V	Lavasorb, 250 mL in Versylene container, singlepack	37207	Fresenius Kabi France 6 rue du Rempart 27400 Louviers (France)
B231515	Lavasorb, 1 000 mL in Versylene container	37207	Fresenius Kabi France 6 rue du Rempart 27400 Louviers (France)