By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 766071 R000

Manufacturer: Fresenius Kabi AG

Address:
Else-Kröner-Str. 1
Bad Homburg
61352
Germany

Single Registration Number: DE-MF-000009273

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2026-10-30**

Current Issue Date: **2026-10-30**

Starting Validity Date: **2026-10-30**

Expiry Date: **2031-10-29**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Device Schedule:

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)	**Intended purpose** (as per the IFU)	**Risk Classification**	**Basic UDI-DI**
Freka-Clyss	1993081 1992081	MDN 1213	The intended purpose of Freka-Clyss is to stimulate/facilitate the evacuation of the bowel.	Class III	4051895NIS95812b000000AC

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3624045	Issued

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