B BRAUN

B. Braun Melsungen AG
Division Hospital Care
34209 Melsungen

Contact: Gudrun Henke

Fon: +49 5661 71-2712
Fax: -
Email: gudrun.henke@bbraun.com
Internet: http://www.bbraun.com

Date: January 29, 2024

To whom it may concern

CONFIRMATION

We,

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Germany

herewith confirm that the following medical devices

Article No.	*Product*	*Classification*
4238010	IN-Stopper	IIa
4238011	IN-Stopper	IIa
4495101	Combi-Stopper	IIa
4495101R	Combi-Stopper	IIa
4495152	Combi-Stopper	IIa
4495209	Combi-Stopper	IIa
5206634	Combifix® Adapter	IIa
5206642	Combifix® Adapter	IIa

are currently placed on the market in accordance with Medical Device Directive MDD 93/42/EEC and will be converted to Medical Device Regulation MDR (2017/745) in the period indicated in the Regulation (EU) 2023/607 until 31st December 2028.

The following medical device

Article No.	*Product*	*Classification*
4097076	Stopper	I sterile

is currently placed on the market in accordance with Medical Device Directive MDD 93/42/EEC and will be converted to Medical Device Regulation MDR (2017/745) with the following new article number

Article No.	*Product*	*Classification*
4097077	Stopper	IIa

in the period indicated in the Regulation (EU) 2023/607 until 31st December 2028.

Additionally we confirm that the following medical devices are currently placed on the market in accordance with Medical Device Directive MDD 93/42/EEC and will not be converted to Medical Device Regulation MDR (2017/745)

Article No.	*Product*	*Classification*
4090306	Combifix® Adapter	IIa
4090705	Verbindungsstück mit loser Überwurfmutter	IIa
4495102	Combi-Stopper	IIa
4495152B	Combi-Stopper	IIa
4597982	Discofix® Verschlusskonus	IIa

For and on behalf of

B. Braun Melsungen AG

i. A.

Aida Sadykova
Senior Manager Regulatory Affairs International
CoE Infusion & Pain Therapy

i. A.

Charlotte Wisker
Administrator Regulatory Affairs International
CoE Infusion & Pain Therapy