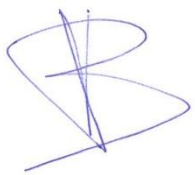
Manufacturer:	BS-Medical Tech Industry SAS
Address:	2 rue de l'Avenir 67470 Niederroedern - France
Authorized representative's name:	Bertrand BASCH
Name of the device:	Ref : 656893 Flocare® DirectPEG CH12 (installation set) Ref : 656707 Flocare® DirectPEG CH14 (installation set) Ref : 673803 Flocare® Safety+ GT CH12 (replacement set) Ref : 673802 Flocare® Safety+ GT CH14 (replacement set) Ref : 673801 Flocare® Safety+ GT CH14 Suction (replacement set with suction)
Lot number:	A dedicated declaration of conformity is established for each batch
Product:	This general DoC (declaration of conformity) covers the above-mentioned references.
Intended purpose of device:	Long-term enteral feeding, especially in for patients who have a functioning gastrointestinal tract and are unable to take adequate oral nutrients.
Classification:	IIb
Notified Body:	TÜV Rheinland
Notified Body address:	TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg · Germany
Notified Body identification number:	CE 0197
CE-Certificate number:	**HD 1957139-1**
CE-Certificate date of validity	2024-05-26
Conformity assessment route:	BS-Medical Tech Industry uses the following procedures for the CE-labelling of their products according the directive 93/42/EEC Class IIb: EC conformity declaration according to annex II without paragraph 4

This declaration of conformity is issued under the sole responsibility of BS-Medical Tech Industry SAS. We hereby declare that the medical device specified above meets the provision of the Directive 93/42/CEE for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by TÜV Rheinland.

All supporting documentation is retained at the premises of the manufacturer.

Name / function: Bertrand Basch, CEO

Signature:



Date: 18/08/2021

Place: Niederroedern