Dansu A/S
Sandbakken 1-3
Ganløse
DK-3660 Stenløse
Tel: +45 48 18 12 74
Fax: +45 48 18 31 86
Email:dansu@dansu.com

EC Declaration of Conformity

Dansu A/S,

Addresss: Sandbakken 1-3, Ganløse, DK-3660 Stenløse, Denmark

Declare, under their sole responsibility, that the medical devices in the family named Non-sterile Foam Applicators indicated in the annexed table:

- are manufactured by **Dansu A/S**,
- are non-sterile medical devices
- have been identified as medical devices in risk class I according to rules 4 and 5 in Annex VIII of Regulation (EU) 2017/745
- meet the applicable provisions, in particular the General Safety and Performance Requirements of the Regulation (MDR) 2017/745 and harmonised standards ISO 14971:2012, ISO 15223-1:2016, and ISO 10993-1:2018
- and are subject to the conformity assessment procedure set out in Annexes II & III, under the self-certification of Dansu A/S.
- All supporting documentation is retained at the premises of the manufacturer.

SRN: Not yet available.

European Representative: Not required.

Basic UDI-DI: 0570655601NFoa04X

Name: DANECHI, Sasan

Function: Director and PRRC

Place: Ganløse

Date: 21.05.2021

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Group	Catalog N°	Description
PS Chock Foam Applicators	12-1153	Green Foam Stick 150x4mm, PS Chock stick
	12-1156	Green Foam stick 150x4mm, PS Choc sticks
	12-1164	Blue Foam Stick 100x4mm, PS Choc stick
	12-1166	Blue Foam stick 150x4mm, PS Choc sticks
	12-1168	Blue Foam Stick 100x4mm, PS Choc stick
	12-1169	Green Foam stick 150x4mm, PS Choc sticks
	32-1150	Green Foam Stick 100x4mm, PS Chock stick
	32-1151	Green Foam stick 100x4mm, PS Choc sticks
	32-1159	Green Foam stick 150x4mm, PS Choc sticks
	32-1162	Blue Foam stick 150x4mm, PS Choc sticks