EU DECLARATION OF CONFORMITY

Valid to: 05-03-2021

DANSAC A/S hereby declares that the company fulfils the obligations concerning the required technical documentation and declares that the products comply with the requirements in the Council Directive of June 14th, 1993 concerning medical devices, (MDD 93/42) and the Danish Medicines Agency Decree no. 1263 of December 15, 2008.

The declaration applies for the following ostomy product in Class I (unsterile):

DANSAC NOVA 2

Dansac Nova 2 is a 2-piece product consisting of a wafer and an ostomy collection pouch. The device is designed for Ostomates.

Date: **05-03-2019**

Signature:

Inge Mygind Aagaard
Manager Quality Assurance
DANSAC A/S
Lille Kongevej 304
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The Dansac Nova 2 range consists of several variants (Ref. and Product Name are listed in the following documents): **FR-DVI2349, FR-DVI2351, FR-DVI2352, FR-DVI2356, FR-DVI2360**

The Pouch:

- Closed or Drainable
- Regular or Mini or Large/Maxi
- Symmetrical or Assymmetrical
- FoldUp (Synomym: Nova 2 EasiFold)
- High Output
- Urostomy

The Wafer:

- Regular Wafer (Synonym: Nova 2 Flange)
- Standard Convex
- Soft Convex
- X3