

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 1

Dansac Nova 1 is a 1-piece product consisting of a ostomy collection pouch with a skin protecting barrier. The device is designed for Ostomates.

Date: **05.03.2019**

Signature:



Inge Mygind Aagaard
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The Dansac Nova 1 range consists of several variants (Ref. and Product Name are listed in the following documents): **FR-DVI2334, FR-DVI2347, FR-DVI2353, FR-DVI2354, FR-DVI2355, FR-DVI2359**

- Regular or Mini or Maxi
- Closed or Drainable
- Symmetrical or Asymmetrical
- FoldUp (Synonym: EasiFold)
- Mini Cap
- Urostomy
- Convex
- X3
- Soft Convex
- Infant
- High Output