

EU DECLARATION OF CONFORMITY

Valid to: 06.03.2021

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 NOVALIFE SOFT CONVEX

Dansac NovaLife 1 Open Soft Convex is a 1-piece product consisting of an ostomy collection pouch with a convex skin protecting barrier.

Dansac NovaLife 1 Closed Soft Convex is a 1-piece product consisting of an ostomy collection pouch with a convex skin protecting barrier.

The devices are designed for Ostomates.

Date: **06.03.2019**

Signature:



Inge Mygind Aagaard
Manager Quality Assurance
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The Dansac NovaLife 1 Soft Convex System range consists of several variants (Ref. Number and Product Name are listed in the following documents): **FR-EVI3309 and FR-EVI3310**.

The Pouch:

- Midi or Maxi
- Closed or Open
- Opaque with Viewing Option