EU DECLARATION OF CONFORMITY

Valid to: 04-03-2021

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 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 OPEN 1&2

Dansac NovaLife Open 1 is a 1-piece product consisting of a ostomy collection pouch with a skin protecting barrier.
Dansac NovaLife Open 2 is a 2-piece product consisting of a ostomy collection pouch and a wafer with a skin protecting barrier.
The device is designed for Ostomates.

Date: **04-03-2019**

Signature:

Inge Mygind Aagaard
Manager Quality Assurance
DANSAC A/S
Lille Kongevej 304
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The Dansac NovaLife Open 1&2 range consists of several variants (Ref. and Product Name are listed in the following document**): FR-EVI3788, FR-DVI2365, FR-DVI2367, FR-DVI2368, FR-DVI3291, FR-DVI3292 and FR-DVI3293**.

The Pouch:

- Mini or Midi or Maxi
- Opaque or Clear
- Opaque with Viewing Option

The Wafer:

- Regular Wafer