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.

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

DANSAC NOVALIFE 1 CONVEX
AND
NOVALIFE 2 CONVEX WAFER

Dansac NovaLife 1 Open Convex is a 1-piece product consisting of an ostomy collection pouch with a convex skin protecting barrier.
Dansac NovaLife 1 Closed Convex is a 1-piece product consisting of an ostomy collection pouch with a convex skin protecting barrier.
Dansac NovaLife 2 Convex Wafer is an ostomy convex skin protecting barrier with a coupling.
The devices are designed for Ostomates.

Date: **04.03.2019**

Signature:

Inge Mygind Aagaard
Manager Quality Assurance
DANSAC A/S
Lille Kongevej 304
DK – 3480 Fredensborg

The Dansac NovaLife 1 Convex and NovaLife 2 Convex Wafer range consists of several variants (Ref. and Product Name are listed in the following document): **FR-EVI3788, FR-EVI3300, FR-EVI3304 and FR-EVI3322**.

The Pouch:

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

The Wafer:

- Regular Wafer