EU DECLARATION OF CONFORMITY

dansac

Valid to: 18.02.2020

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).

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

DANSAC X-TRA STRIPS

Product description:

Dansac X-tra Strips – Barrier Extenders are ostomy products consisting of skin protecting material, formed as a semicircle, mounted with a release film/paper and supplied in a protecting moulded form. The products are used to fill and level skin folds and crevices of the skin around the stoma by extending the barriers and thereby increasing the barrier adhesion.

Date: 18.02.2018

Signature:

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

The Dansac X-tra Strips range consists of the following variants (Ref. and Product Name are listed in the following document): **FR-DVI2329**