EC Declaration of Conformity to Council Directive 93/42/EEC and amendments concerning Medical Devices

Manufacturer	Coloplast A/S Holtedam 1 3050 Humlebaek Denmark
Product	Product family: Ostomy bags (refeeding)
	Product name: SenSura Mio/Coloplast Baby ostomy bag, 2-piece
Description	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 31076 Open-ended intestinal ostomy bag, multiple-piece
EC Product Class according to Annex IX	Class: Sterile class IIa Rule no.: 2
Notified Body	DNV GL Presafe AS (2460) Veritasveien 3, N-1363 Høvik, Norway
ID no.	474

The undersigned, Director, Regulatory Affairs and Biosafety, declares that the following devices:
SenSura Mio/Coloplast Baby ostomy bag, 2-piece
conform to the relevant provisions of the European Communities' Council Directive 93/42/EEC and amendments and are in accordance with:
Annex II Conformity Assessment Procedure (full quality assurance system) as verified by the DNV GL Presafe AS (2460).

This product was originally CE-marked: 02/07/2019

Date: 15 DEC 2020 By: _____

Joan Drejer
Director, Regulatory Affairs and Biosafety

Description on Primary Packaging for

Product family:
Ostomy bags (refeeding)

Product name:
SenSura Mio/Coloplast Baby ostomy bag, 2-piece

Item number	Product name	Product description	Date of the original CE-marking
18700	SenSura Mio/Coloplast	Baby ostomy bag, 2-piece Flex, with soft spout outlet, Neutral grey, No filter	02-07-2019

Date: 15 DEC 2020 By: _____

Joan Drejer
Director, Regulatory Affairs and Biosafety