



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: Purilon Gel
	Product name: Purilon Gel
Description	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 47764 Wound Hydrogel dressing, sterile
EC Product Class according to Annex IX	Class: Sterile class IIb Rule no.: 4
Notified Body	Presafe Denmark A/S - (0543) Tuborg Parkvej 8, DK-2900 Hellerup, Denmark
ID no.	229

The undersigned, Director, Global Regulatory Affairs, declares that the following devices:
Purilon Gel
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
Presafe Denmark A/S - (0543).

This product was originally CE-marked: 23/01/1997

25 OCT 2019

Date: _____ By: _____
Joan Drejer
Director, Global Regulatory Affairs

Description on Primary Packaging for

Product family:

Purilon Gel

Product name:

Purilon Gel

Item number	Product name	Product description	Date of the original CE-marking
3900 / 03900	Purilon Gel	Purilon Gel, 15 g	23-01-1997
3903 / 03903	Purilon Gel	Purilon Gel, 25 g	23-01-1997
3906 / 03906	Purilon Gel	Purilon Gel, 8 g	01-10-1999

Date: **25 OCT 2019** By: 
Joan Drejer
Director, Global Regulatory Affairs