



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

<b>Manufacturer</b>	Coloplast A/S Holtedam 1 3050 Humlebaek Denmark
<b>Product</b>	Product family: Peristeen Anal Plugs
	Product name: Peristeen Anal Plug
<b>Description</b>	On primary packaging: See attachment
	Global Medical Device Nomenclature code/name: 46193 Anal plug, single-use
<b>EC Product Class according to Annex IX</b>	Class: Non-sterile class IIb Rule no.: 5
<b>Notified Body</b>	DNV GL Presafe AS (2460) Veritasveien 3, N-1363 Høvik, Norway
<b>ID no.</b>	45

The undersigned, Director, Regulatory Affairs and Biosafety, declares that the following devices:  
Peristeen Anal Plug  
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: 15/12/1994

Date: 15 DEC 2020 By:   
Joan Drejer  
Director, Regulatory Affairs and Biosafety

## Description on Primary Packaging for

**Product family:**

Peristeen Anal Plugs

**Product name:**

Peristeen Anal Plug

Item number	Product name	Product description	Date of the original CE-marking
1450 01450	Peristeen Anal Plug	Small 1 tube of gel Expanded Ø 37 mm Ø 12 mm Length 26 mm	15-12-1994
1451 01451	Peristeen Anal Plug	Large 1 tube of gel Expanded Ø 45 mm Ø 13 mm Length 26 mm	15-12-1994
29002	Peristeen Anal Plug	Anal Plug Starterpack 2x 1450 1-piece plug, Ø 12 mm Length 26 mm, Small, Expanded Ø 37 mm 2x 1451 1-piece plug, Ø 13 mm Length 26 mm, Large, Expanded Ø 45 mm 1x Tube gel	15-12-1994
29004	Peristeen Anal Plug	Anal Plug Starterpack 2x 1450 1-piece plug, Ø 12 mm Length 26 mm, Small, Expanded Ø 37 mm 2x 1451 1-piece plug, Ø 13 mm Length 26 mm, Large, Expanded Ø 45 mm 1x Tube gel	15-12-1994

Date: **15 DEC 2020**

By:   
Joan Drejer  
Director, Regulatory Affairs and Biosafety