Confidential

Coloplast
Ostomy Care
Continence Care
Wound & Skin Care
Interventional Urology

To whom it may concern

February 16th, 2021

Important note
Coloplast considers the existence and contents of this document to be confidential and exempt from public disclosure. This information should be transmitted to relevant authorities for registration purposes only.

Declaration Letter

Legal Manufacturer according to Medical Device Directive 93/42/EEC

Coloplast A/S
Holtedam 1,
3050 Humlebaek
Denmark

We, Coloplast A/S, Holtedam 1, 3050 Humlebaek, Denmark, hereby confirms that the device listed in Appendix 1 conforms to the essential requirements in Annex I of the Medical Device Directive 93/42/EEC with respect to the below intended use.
Refer to documents *EC declaration of conformity* ***#288 X-FLOW Prostatectomy Catheter Silicone,*** and ***Essential Requirements - Silicone Prostatic Catheter*** joined to this Declaration letter.

Intended use:
The silicone prostatic catheters are intended to be used after prostatectomy or bladder surgery for
- Short-term drainage of bladder urine
- Postoperative bladder irrigation-lavage
- After prostate surgery: haemostasis of the prostatic fossa

The device can be used for up to 7 days. Prostatic catheters must not be left in place for more than 7 days.

As per the Clinical Investigation Plan title: OPTION – OutPatienT InductiON. Labour induction in an outpatient setting - a multicenter randomized controlled trial, the essential requirements of the device listed in Appendix 1 do not cover the aspects subject to the investigations, however every precaution has been taken to protect the health and safety of the patient on all other aspects. Refer to" Investigator Brochure X-FLOW®

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Prostatectomy short catheter straight tip 3-way 30-50 ml silicone CH FR 22- OPTION OutPatienT InductiON" and Essential Requirements - Silicone Prostatic Catheter joined to this Declaration letter.

Based on:

- The general knowledge of the device,
- The previous experience with comparable devices, used in same indication as that of the study,
- The clinical and research level of the Swedish investigators team, presenting with a large experience and a high-level expertise in obstetrics and gynecology with numerous studies and publications in peer-reviewed journals,

Based on:

- The quality level of the study protocol, to be performed at a national-wide scale in numerous Swedish centers, over a large sample size of randomized women, and to be conducted in accordance with international and local regulations, including Good Clinical Practice – ICH, Ethics committee approval, Swedish Medical Agency, under the sponsorship and responsibility of a highly trained investigators team,

And based on the thorough definition of patients and follow-up of safety data as planned in the Clinical Investigation Plan, for both peri-natal and maternal outcomes, with:

- The precise mention of inclusion and non-inclusion criteria related to the study and to the studied device,
- The precise follow-up plan of included patients,
- The focus on identified/expected safety data, and the systematic tracking and record of any safety data (AE, SAE), and any device effect (SADE, USADE), well defined in the clinical plan, to be evaluated and further reported as needed according to regulation,
- The independent monitoring of the study process,
- The details of planned interim analysis and publications,

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it is assumed that the studied device will be used in acceptable conditions as regards to patients' safety.

Date: February 16h, 2021

Signature

Name: Stephane Bouche
Job Title: Senior Regulatory Affairs Manager

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Appendix 1

Table 1: List of the devices covered by the statement

Ref.	Product name/description
AB6H22	X-FLOW® Prostatectomy short catheter straight tip 3-way 30-50 ml silicone CH FR 22