Puritan
Quality since 1919

Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Puritan Medical Products Company LLC
Manufacturer address and contact details	31 School Street Guilford, ME 04443 kmwrigley@puritanmedproducts.com
Single Registration Number (SRN)	US-MF-000007051

Authorised Representative name	Emergo Europe
Authorised Representative address and contact details	Westervoortsedijk 60 Arnhem 6827 AT, Netherlands Natalia.Kolarovicova@ul.com
Single Registration Number (SRN)	NL-AR-000000116

Notified body name	BSI Group The Netherlands B.V.
Notified body number	2797
Directive Certificate number(s) to which this confirmation is made	CE 02076
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	2023-09-15
End date of extended validity/transition period	2028-12-31

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate,** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*

Puritan
Quality since 1919

- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above and in the attached schedule:

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.
- Directive Certificate(s) covering the listed device(s) expired/expires *after* 20 March 2023.
- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

➢ **Device(s) as listed in the attached schedule:**

- The device(s) continue to comply with the AIMDD or MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

9/15/2023

Kevin Wrigley, Director of Quality Systems & Regulatory Affairs
Puritan Medical Products Company, LLC
31 School Street
Guilford ME, 04443
kmwrigley@puritanmedproducts.com

Date

Puritan
Quality since 1919

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
• Sterile Tongue Depressors • Sterile Absorbent Tipped Applicators • Sterile Cervical Brushes • Sterile Absorbent Tipped Specimen Collection Devices	CE 02076	2023-09-15	BSI 2797	BSI 2797	2028-12-31	N/A