(T52) Declaration of Conformity

FRM-507867, V3.0

GSK Consumer Healthcare

Document No./Name:20	**Version Number: 9 (CC1160306)**
Issue date: 20 MAY 2020	**Valid to date:** 20 MAY 2025

Completed by Manufacturer:

Name of Manufacturer:	GSK Consumer Healthcare (GMDT)
Address of Manufacturer:	GSK Consumer Healthcare (GMDT), Clocherane, Youghal Road, Dungarvan, Co. Waterford, Ireland
Name of Device:	Biopsy Punch & Curette
Intended Use:	The devices are sterile, invasive devices for transient use to be used in the area of minor surgical procedures. They are intended for single use only
Device Classification:	Class IIa Rule 6
Notified Body and number:	**SGS Belgium NV,** SGS House Noorderlaan 87 2030 Antwerp Belgium **Notified Body number: 1639**
Product Lines and Formula Number:	**Biopsy Punch:** 2.0mm (62377), 3.0mm (62376), 3.5mm (61463), 4.0mm (62375), 5.0mm (62366), 6.0mm (62374), 8.0mm (62373) **Curette:** 4.0mm (70592), 7.0mm (61569)
Batch number:	All lots released from/All lots manufactured from May 2020 until such time as significant changes are made to product, its starting materials or key subcontractors.

Address of Fabrication Site(s):	**Formula Supplied from Fabrication Site:**
sfm medical devices GmbH Bruckenstrasse 5, 63607 Wachtersbach, Germany	Biopsy Punch & Curette
SaFeMed spol.s.r.o. Trabantska 292, 19015 Praha 9/Satalice, CZECH REPUBLIC	Curette - moulding of the protection cap for the curettes, overmoulding the blade and packaging only.

We, the undersigned, hereby declare that the medical device specified above conforms to the Essential Requirements listed in Annex I of Council Directive 93/42/EEC (as amended by directive 2007/47/EC).

The required technical documentation has been prepared and is available to the national authorities for inspection purposes.

Completed/confirmed by Regulatory:

Standard	Sections	Title
BS EN ISO 11135: 2014	Sterilization of health care products	BS EN ISO 11135: 2014

This declaration is supported by EC Quality Certificate Annex V No. GB20/965119 issued by SGS Belgium NV, Notified Body No. 1639 and Quality System Approval Certificate GB19/963036.

	Management Representative/Legal Manufacturer	**Regulatory Affairs, signing to confirm that the Essential Requirements are met.**
Place	GMDT Ireland and UK	Stockley Park, Middlesex, UK
Date	08 May 2020	18 MAY 2020
Signature	Tara Roche	
Full Name	Tara Roche	Umran Anwar
Position	Compliance Manager GSK Consumer Healthcare (GMDT)	Regulatory Affairs Management Manager

(GSK staff to confirm any proposed registrations with named manufacturer)

Template revision history

REVISION
(Principal Changes from last revision)

Type of change: ☐ New ☒ Revision with minor changes;
☐ Revision with major changes impacting:
☐ Roles and responsibilities
☐ process or activities

Reason for Change:
Existing SGS Annex V certificate split into 5 separate certificates.

Description of Change:
DofC20 v 9 raised on updated DofC template v 3.0