

EUROPEAN DECLARATION OF CONFORMITY

1. ANNEX IV OF THE REGULATION (EU) 2017/745

1	Manufacturer:	Name, registered trade name or registered trade mark, SRN per in Article 31 GlaxoSmithKline Trading Services Limited, (Company No. 406446) SRN: IE-MF-000008351		
	Address:	12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland		
	Authorised Representative:	Not applicable		
	Address:	Not applicable		
2	This EU declaration of conformity is issued under the sole responsibility of the manufacturer			
3	The Basic UDI-DI:	Curette	5054363591471876DH	
4	Product & trade name:	Curette		
	Product code:	See Appendix A		
	Intended purpose:	Curette is a device for skin tissue removal, including excision of superficial lesions.		
5	Risk classification (<i>Annex – VIII</i>):	Class IIa according to Rule 6		
6	Devices in section 4 are in conformity with REGULATION (EU) 2017/745			
7	Reference to CS:	NA		
8	Notified Body:	BSI Group the Netherlands B.V.		NB No.: 2797
	Conformity assessment procedure:	Examination of the technical documentations as per Annex IX Chapter I and III of the REGULATION (EU) 2017/745		Certificate No. MDR 732117 R000
9	Other Information:	None		
10	Place of Issue:	GSK Trading Services Ltd	Name of person:	Mary McQuaid
	12, Riverwalk, City West, Dublin 24, Ireland		Function:	Medical Device Regulatory Compliance Manager
	Date of Issue: Refer to electronic date of approval		Signature: Refer to electronic approval signature	

2. APPENDIX A

Product Description	Central Product Code	Supplier Local Product Code	Device UDI-DI	Pack UDI-DI (Carton)	Outer Pack UDI-DI (Case)
Curette 7mm (10)	60000000000558	61569	85054363000314	05054363000318	25054363000312
Curette 4mm (10)	60000000000559	70592	85054363000321	05054363000325	25054363000329

3. VERSION HISTORY

Revision number	Reason
01	New document
02	Updated sections section 3.2, MAN 1 and MAN 3 as per CHC-000191
03	Updated Section 2.1 and Section 10 (LAB 2) as per CHC-002576
04	<u>CHC-004273</u> Updated Section 2.1, Section 9.1, MAN 1, MAN 3 <u>CI-003935</u> 5.2, 5.3, 5.4, RMR1, MAN 1, MAN 3
05	<u>CPA-028329</u> Updated Section 1.4, Added BOM 7 <u>Additional update</u> Updated Section 4.1

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Approval	Mary McQuaid I am approving the content of this document and authorize its issuance. 21-Jul-2023 14:36:27 GMT+0000
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