

## EUROPEAN DECLARATION OF CONFORMITY

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

1	Manufacturer:	<i>Name, registered trade name or registered trade mark, SRN per in Article 31</i> 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: <b>Refer to electronic date of approval</b>	Signature: <b>Refer to electronic approval signature</b>		

## 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

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Approval	Mary McQuaid I am approving the content of this document and authorize its issuance. 04-Nov-2022 10:26:17 GMT+0000
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