

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:	Biopsy Punch	5054363591190830BZ	
4	Product & trade name:	Biopsy Punch		
	Product code:	See Appendix A		
	Intended purpose:	The Biopsy Punch is intended to be used in a skin biopsy procedure.		
5	Risk classification (Annex – VIII):	Class IIa based on Rule 6		
6	Device in section 4 is 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 Chapters 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 approval date	Signature: Refer to electronic 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)
BIOPSY PUNCH 2MM (10)	60000000000557	62377	85054363000307	05054363000301	25054363000305
BIOPSY PUNCH 3MM (10)	60000000000564	62376	85054363000376	05054363000370	25054363000374
BIOPSY PUNCH 3.5MM (10)	60000000000565	61463	85054363000383	05054363000387	25054363000381
BIOPSY PUNCH 4MM (10)	60000000000563	62375	85054363000369	05054363000363	25054363000367
BIOPSY PUNCH 5MM (10)	60000000000562	62366	85054363000352	05054363000356	25054363000350
BIOPSY PUNCH 6MM (10)	60000000000561	62374	85054363000345	05054363000349	25054363000343
BIOPSY PUNCH 8MM (10)	60000000000560	62373	85054363000338	05054363000332	25054363000336

3. VERSION HISTORY

Revision number	Reason
01	New document
02	Updated section 1.4 BOM as per CPA-000180
03	Updated Section 2.1 and Section 10 (LAB2) as per CHC-002576
04	<u>Updated as per CI-002988</u> Updated Section 3.2, 5.3, 5.4, MAN 1. Added two new Section 10 documents - RMR 1 and MAN 3.
05	<u>CHC-004251</u> Updated Section 2.1, MAN1, MAN3, 9.1
06	<u>CPA-028313</u> Updated Section 1.4, Added BOM 7C <u>Additional update</u> Updated Section 4.1
07	<u>CA-049714</u> Updated section 3.2, 6.5, CVA4

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Approval	Mary McQuaid I am approving the content of this document and authorize its issuance. 10-Aug-2023 14:59:41 GMT+0000
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