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:	Biopsy Punch	5054363591190830BZ	
4	Product & trade name:	Biopsy Punch		
	Product code:	See Appendix A		
	Intended purpose:	The Biopsy Punch is intended to make a cylindrical incision in skin tissue which has been clinically assessed as suitable for removal.		
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:	Person Responsible for Regulatory Compliance, GlaxoSmithKline Trading Services Limited.
	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	89753	85054363000307	05054363000301	25054363000305
BIOPSY PUNCH 3MM (10)	60000000000564	89754	85054363000376	05054363000370	25054363000374
BIOPSY PUNCH 3.5MM (10)	60000000000565	89755	85054363000383	05054363000387	25054363000381
BIOPSY PUNCH 4MM (10)	60000000000563	89756	85054363000369	05054363000363	25054363000367
BIOPSY PUNCH 5MM (10)	60000000000562	89757	85054363000352	05054363000356	25054363000350
BIOPSY PUNCH 6MM (10)	60000000000561	89758	85054363000345	05054363000349	25054363000343
BIOPSY PUNCH 8MM (10)	60000000000560	89759	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	Updated as per CI-002988 Updated Section 3.2, 5.3, 5.4, MAN 1. Added two new Section 10 documents - RMR 1 and MAN 3.
05	CHC-004251 Updated Section 2.1, MAN1, MAN3, 9.1
06	CPA-028313 Updated Section 1.4, Added BOM 7C Additional update Updated Section 4.1
07	CA-049714 Updated section 3.2, 6.5, CVA4
08	CPA-064718 ➢ Updated Section 8.1, Declaration of conformity, Part 4 Intended Purpose y to align with the intended purpose as defined in Section 1.1 DDS – Description Specification. CPA-065254 ➢ Updated Sections 6.2 CPA-062470 ➢ Updated RMR 1, 5.3, 5.4, HARA 2. Additional updates • Updated Section 8.1, Declaration of conformity, Part 10 Function from 'Medical Device Regulatory Compliance Manager' to 'Associate Director, Medical Devices'. • Added MAN 3 version 4.0, PAC 1, 2, 3 (version 1.0) to the binder – these documents are referenced within the corresponding technical file sections. • Removed GSPR 1, 2, 3 (version 1.0) from the binder - these documents are no longer referenced within the corresponding technical file section via updates made to Section 4.1 GSPR Checklist version 2.0.

09	**CPA-045182** • Updates to sections – Administrative, 1.1, 1.2,3.4, 7.1 **Periodic review** • Updates to the following sections:, 1.3, 1.4, 3.1, 3.2, , 3.3, 4.1, 4.2, 5.1, 5.2, 5.3, 5.4, 6.1, 6.2, 7.2, 9.1. • Addition of 1 x addenda to Section 6.4 • Addition of Section 7.4 PSUR - MD Biopsy Punch 01Jan2021-31Oct2023 (v2.0) • Removal of 7.4-PSUR - MDTF_Periodic Safety Update Report_Biopsy punch 1.0
10	**CPA-073795** • Updates to Section 2.1.
11	**ACT-066450** • Updates to Section 4.1
12	**CPA-088015** • Updates to section 6.2 • Section 10 reference PVASL 1 updated
13	**CA-029418** • Update to Section 1.3 • Addition of DRA 8-14 **ACT-067276** • Updates to Section 3.2, 6.2 • Addition of PVASL 4, 5
14.0	**CA-176557** • Updates to Sections 1.1, 1.3, 1.4, BOM 10 and addition of 6.1 Addendum. **Additional changes** • Updated function from 'Associate Director, Medical Devices' to 'PRRC'.
15.0	**CHC-000197, CA-039412** • Update to Section 3.2 • Update to MAN 1, MAN 2, MAN 3 **CA-176537** • Updates to Section 1.1, 1.3 • DRA 1-7 updated • Removal of DRA 8-14 • Updates to Section 9.1 **ACT-128692** • Updates to Section 4.2

Signature Page for RPS-MD-000033 v15.0

Approval	Mary McQuaid I am approving the content of this document and authorize its issuance. 08-Jul-2025 09:24:56 GMT+0000

Signature Page for RPS-MD-000033 v15.0