



EU Declaration of Conformity
according to Regulation (EU) 2017/745 of the European Parliament
and of the Council of 5 April 2017 on Medical Devices

Medical Device Group	Single-Use Biopsy Devices
Basis UDI-DI according to Annex VI, Part C	42511358000001DL
Intended Purpose	The biopsy device is intended for removal of soft tissue samples for histological examination. It is intended for single-use and transient invasive application
Classification according to Annex VIII	Ila
Device Group according to EMDN	A010201 – NEEDLES AND KITS – HISTOLOGICAL AND CYTOLOGICAL BIOPSY OF SOFT TISSUES

Products:

Product Code (Article number)	Trade Name	Suffix	Extension
HCXXYYY	BIP HistoCore® Biopsy Device, disposable		
HCXXYYT	BIP HistoCore® T Biopsy Device, disposable		WingTip-Trocar®
HCXXYYTX	BIP HistoCore® TX Biopsy Device, disposable	with Coaxial Cannula	WingTip-Trocar®

X stands for diameter dimensions [Gauge], Y for length dimensions [mm] of product variants.

List(s) of product variants: see appendix

Manufacturer	BIP Biomedizinische Instrumente und Produkte GmbH Am Brand 1 82299 Türkenfeld Germany
Single Registration Number of manufacturer according to Article 31	DE-MF-000010311

We hereby declare on our sole responsibility the conformity of the abovementioned medical devices in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices:

We hereby ensure that the medical devices that are covered by the present declaration are in conformity with Regulation (EU) 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Applied Common Specifications (CS)

Common Specification(s)	none
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Notified Body	TÜV SÜD Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany Identification number 0123
Conformity assessment procedure performed	Annex IX Chapters I and III
Certificate(s) issued	EC Certificate G10 020818 0020 Rev.00 valid until 2029-10-29
EU Declaration of Conformity is valid until	2029-10-29

Signed on behalf of BIP Biomedizinische Instrumente und Produkte GmbH

Thomas Heske

Türkenfeld, 2025-01-13

Executive Management
(CEO)

Place, Date





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APPENDIX – List of product variants with Product Codes (Article numbers)

BIP HistoCore®	BIP HistoCore® T	BIP HistoCore® TX
HCXXYYY	HCXXYYT	HCXXYYTX
HC12100	HC12100T	HC12100TX
HC12130	HC12130T	HC12130TX
HC12160	HC12160T	HC12160TX
HC12200	HC12200T	HC12200TX
HC14100	HC14100T	HC14100TX
HC14130	HC14130T	HC14130TX
HC14160	HC14160T	HC14160TX
HC14200	HC14200T	HC14200TX
HC14250	HC14250T	
HC16100	HC16100T	HC16100TX
HC16130	HC16130T	HC16130TX
HC16160	HC16160T	HC16160TX
HC16200	HC16200T	HC16200TX
HC16250	HC16250T	
HC18100	HC18100T	HC18100TX
HC18130	HC18130T	HC18130TX
HC18160	HC18160T	HC18160TX
HC18200	HC18200T	HC18200TX
HC18250	HC18250T	HC18250TX
HC20100		
HC20130		
HC20160		
HC20200		
HC20250		