PROCEPT BioRobotics

DECLARATION OF CONFORMITY
MEDICAL DEVICES

Product Name	HYDROS Robotic System
Intended Purpose	Intended Use: The HYDROS® Robotic System is intended for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms (LUTS).
Legal Manufacturer:	PROCEPT BioRobotics Corporation 150 Baytech Drive, San Jose, CA 95134
Manufacturer Single Registration Number (SRN)	US-MF-000015560
Authorized Representative:	QualRep Services B.V. Utrechtseweg 310 – Bldg B42 NL-6812 AR Arnhem The Netherlands T: + 31-20-78 82 630 Email: globalreg@qservegroup.com Website: www.qservegroup.com
Authorized Representative Single Registration Number (SRN)	NL-AR-000000537
Notified Body (NB):	BSI, Netherlands NB Number: 2797 Say Building, John M Keynesplein 9, 1066 EP Amsterdam, The Netherlands

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Conformity Assessment Procedure:

Article 52 (4)
Manufacturers of class IIb devices, other than custom-made or investigational devices, shall be subject to a conformity assessment as specified in Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of that Annex of at least one representative device per generic device group.

Applicable CE Certificate(S)

Certificate Type	Certificate Number	Issued By in accordance with requirements of MDR	Original Registration Date (First Issue Date)	Effective Date (Current Issue Date)
EC Certificate Regulation (EU) 2017/745	MDR 728071	BSI	2022-05-04	2025-05-12

Device Name and Model information:

Model Number	Device Name	Basic UDI-DI	Risk Class	Rationale for Risk Class as per MDR 2017/745
HY1000	HYDROS Robotic System	0850055427HY1000QB	Class IIb	Rule 9 (first paragraph) Rule 11 (second indent)

Common Specifications complied with: N/A

This Declaration of Conformity is issued under the sole responsibility of the manufacturer, PROCEPT BioRobotics Corporation.

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We hereby declare that the above mentioned devices comply with the relevant Union harmonisation legislation:

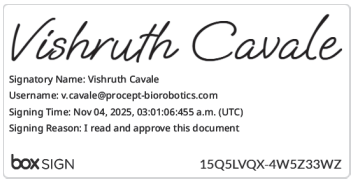
- European Medical Device Regulation 2017/745
- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2) as amended by EU/2015/863. Directive 2014/53/EU Radio Equipment Directive (RED)
- EU Battery Regulation (2023/1542)

Document Prepared By:

Name: Ishita Raje, Vishruth Cavale

Role and Function: Senior Regulatory Affairs Specialist

Signature:



Date (DD/MMM/YYYY):

Nov 3, 2025 Nov 3, 2025

Authorized Signatory on Behalf of Legal Manufacturer
(Signed by PRRC or his/her delegate)

Name: Ankur Kaushal

Role and Function: VP, Global Regulatory Affairs

Signature:

Place of Issue: PROCEPT BioRobotics Corporation, San Jose, CA USA

Date of Issue (DD/MMM/YYYY): Nov 3, 2025

Revision History

Rev. Date dd/mmm/yyyy	Change Description	Reason for Change	Author
A Per PLM	Initial CE marking of HYDROS Robotic System	New generation device added to MDR CE Certificate.	Ishita Raje and Vishruth Cavale