Declaration of Conformity

Declaration Number:	DC-01	**Product Family Name:**	Contrelle® Activgard
CE Certification ID:	PGH – 2020-005 rev2	**Description:**	Vaginal pessary for the treatment of female stress urinary incontinence
Date:	11-Dec -2023	**Product Classification:**	Class IIa (Rule 5)
Manufacturer:	Viveca Biomed Ltd Unit 1 & 2 Wansbeck Network Centre Rotary Parkway Ashington Northumberland NE63 8QU, UK	**Conformity Assessment:**	MDD Annex II – Full Quality Assurance (exc. Section 4)
		Basic UDI:	506077227V01EB

Product Configuration and Identification:

Product Designations		Region		Language Specific	
VXX0001P5	Activgard 5 Pack - Size 1	V01	UK / Ireland / South Africa / Australia	V01	English
VXX0002P5	Activgard 5 Pack - Size 2	V02	Germany / France / Italy	V52	German
VXX0003P5	Activgard 5 Pack - Size 3	V03	Denmark / Norway	V53	French
VXX0001P30	Activgard 30 Pack - Size 1	V04	Sweden / Finland	V54	Italian
VXX0002P30	Activgard 30 Pack - Size 2	V05	Spain / France / Netherlands	V55	Danish
VXX0003P30	Activgard 30 Pack - Size 3	V06	Estonia / Latvia / Lithuania	V56	Norwegian
VXXSP	Activgard Sizing Kit	V07	Kuwait / Bahrain / Qatar / Egypt / Saudi Arabia / United Arab Emirates	V57	Swedish
VXXSP2	Activgard Sizing Kit - Soft Pack	V08	Poland / Czech / Ukraine	V58	Finnish
				V59	Spanish
				V60	Dutch
VXX	Region/Language Code			V61	Estonian
				V62	Latvian
				V63	Lithuanian
				V64	Arabic
				V65	Polish
				V66	Czech
				V67	Ukrainian

Applicable Standards and Guidelines
ISO 13485, EN ISO 10993-1, ISO 10993-1, EN ISO 10993-5, ISO 10993-5, BS EN ISO 10993-10, ISO 10993-10, BS EN ISO 14971, ISO 14971, EN 1041 + A1, BS EN 1041:2008+A1, BS EN ISO 15223-1, ISO 15223-1, MEDDEV. 2.7.1, MEDDEV 2.12/2, BS EN ISO 14155

Declaration

- Viveca Biomed Ltd hereby declares that the device specified above conforms with the Essential Requirements of the Medical Device Directive - 93/42/EEC of June 14, 1993 as amended by Directive 2007/47/EC of 21st September 2007.
- The stated products are designed and manufactured by Viveca Biomed Limited, in accordance with the scope of a quality system which meets the requirements of ISO 13485:2016 and the Medical Devices Directive - 93/42/EEC.
- Viveca Biomed Ltd Notified Body (1282) ENTE Certificazione Macchine SRL (ECM), Via Ca' Bella, 243/A – loc. Castello di Serravalle 40053 Valsamoggia (BO) Italy has approved the manufactures full quality assurance system.
- CS Life Sciences Europe Ltd, The Black Church, St. Mary's Place, Dublin 7, D07 P4AX, Ireland has been appointed to act for Viveca Biomed Ltd within the European Union as their Authorised Representative.
- This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer).

Authorised By:

Andrew P Tasker
Andrew P Tasker (Dec 11, 2023 13:44 GMT)

Andrew Tasker - CEO

11-Dec-2023 - DoC - FINAL

Final Audit Report 2023-12-11

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"11-Dec-2023 - DoC - FINAL" History

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