Title:

Template Doc ID	VV-00024
Template Version	2.0

EU DECLARATION OF CONFORMITY

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This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer:	**BioClin B.V.** Blaak 555 3011 GB Rotterdam, The Netherlands **SRN:** NI-MF-000006004
General product name:	Multi-Gyn ActiGel 2in1
Trade name(s)	▪ ActiGel 2in1 ▪ NatuCare ▪ FloraBalance
Variants/package sizes	Multi-Gyn ActiGel 50 ml aluminium tube Multi-Gyn NatuCare 40 ml aluminium tube Multi-Gyn FloraBalance 50 ml aluminium tube
Basic-UDI	87142071005008ME
Intended purpose of the device:	Multi-Gyn ActiGel 2in1 and, NatuCare is intended for: - Treatment of Bacterial Vaginosis - Reduction of odour and discharge of the vagina - Restoration of vaginal pH and flora - Treatment of vaginal symptoms and discomfort like itch, irritation, sensitivity, redness and soreness, abnormal discharge. Multi-Gyn FloraBalance is intended for: - Restores, strengthens and protects vaginal flora - Supports 'friendly' lactobacilli - Balances pH
Risk class	Class IIb (in accordance with the rules set out in Annex VIII of the Medical Device Regulation 2017/745 (MDR))
Conformity assessment procedure:	Annex IX Quality management system assessment; Chapter I. Section 2. of the Medical Device Regulation 2017/745 (MDR)
Certificate of CE marking of conformity:	Certificate number: 7168GB448240116 Certificate date: 15 January 2024 Notified Body: MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg

Title:

Template Doc ID VV-00024
Template Version 2.0

EU DECLARATION OF CONFORMITY

	Notified Body identification number: 0482
Quality System based on the harmonized standards ISO 13485:	Certificate number: 7168GB445240115. Certificate date: First issued 15 January 2024, Reissued N/A, Valid until 12 April 2025. Notified Body: MEDCERT GmbH, Pilatuspool 2, 20355 Hamburg Notified Body identification number: 0482
We, the manufacturer hereby declare, that the device that is covered by the present declaration is in conformity with the Medical Device Regulation 2017/745 (MDR) with its amendments, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity, as well as with the applicable harmonized standards (as published in the Official Journal of the European Communities).	
Place and date:	Stockholm, Sweden 2024-07-24
Name and function:	Jasmine Vinnfall Person Responsible Regulatory Compliance Karo Healthcare AB/BioClin B.V.
Signature:	

Title:

Template Doc ID	VV-00024
Template Version	2.0

EU DECLARATION OF CONFORMITY

Article no	Trade name	Package size	Market
1001976	MULTI-GYN ACTIGEL 2in1	Tube 50 ml	Germany/Austria/Switzerland
1002995	MULTI-GYN ACTIGEL 2in1	Tube 50 ml	Spain
1002280	MULTI-GYN ACTIGEL 2in1	Tube 50 ml	United Kingdom
1002942	MULTI-GYN ACTIGEL 2in1	Tube 50 ml	United Kingdom/France - Amazon
1002231	MULTI-GYN ACTIGEL 2in1	Tube 50 ml	International
1002174	MULTI-GYN ACTIGEL 2in1	Tube 50 ml	Italy
1002749	MULTI-GYN ACTIGEL 2in1	Tube 50 ml	Italy - Amazon
1001986	MULTI-GYN ACTIGEL 2in1	Tube 50 ml	Netherlands/Belgium
1002279	MULTI-GYN ACTIGEL 2in1	Tube 50 ml	Norway/Denmark
1002175	MULTI-GYN ACTIGEL 2in1	Tube 50 ml	Sweden/Finland
1003552	MULTI-GYN FLORABALANCE	Tube 50 ml	Germany/Austria/Switzerland
1003642	MULTI-GYN FLORABALANCE	Tube 50 ml	DE/UK/ES/IT - Amazon
1003731	MULTI-GYN FLORABALANCE	Tube 50 ml	Sweden
1003002	MULTI-GYN NATUCARE	Tube 40 ml	United Kingdom/France/Italy/Spain /Germany - Amazon
1003004	MULTI-GYN NATUCARE	Tube 40 ml	Netherlands