

EU Quality Management System Certificate

Certificate no. 7250GB448230503 Final Assessment Report no. 7250AU09F

Effective date 2023-05-03

Expiry date 2027-05-15

This is to certify that the quality system of

pjur group Luxembourg S.A.

87, esplanade de la Moselle, 6637 Wasserbillig, Luxembourg

SRN: LU-MF-000000315

For design, production, and final product inspection/testing of Medical devices/groups of medical devices listed on the following pages

Has been assessed and found to comply with respect to

The conformity assessment procedure described in Annex IX Chapter I of Regulation (EU) 2017/745 on Medical Devices

Any applicable limitations for certain medical devices are included in the following list or recorded in the final assessment report. This certification is subject to surveillance by DNV MEDCERT.

Place and date Hamburg, 2023-05-03

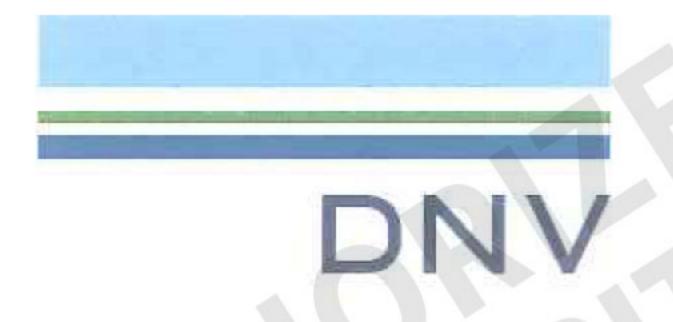


BS-MDR-096

For the issuing office DNV MEDCERT GmbH - Notified Body 0482 Pilatuspool 2, 20355 Hamburg, Germany

Marcus Harder Director Certification

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de



Certificate no. 7250GB448230503
Place and date Hamburg, 2023-05-03

Sites covered by this certificate

pjur group Luxembourg S.A., 87, esplanade de la Moselle, 6637 Wasserbillig, Luxembourg pjur group Luxembourg S.A., 84, esplanade de la Moselle, 6637 Wasserbillig, Luxembourg



Certificate no. 7250GB448230503 Place and date Hamburg, 2023-05-03

Products covered by this certificate

Class IIb medical devices

Category EMDN code Medical devices/groups of medical devices

MDN 1213 U0803 Vaginal devices in the form of solutions/creams/ova/tablets

Intended purpose

Lubricants for alleviation of vaginal dryness and / or as accessories for use with condoms



MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 7250GB445230503

Final assessment report no. 7250AU09F

Effective date 2023-05-03

Expiry date 2025-05-15

This is to certify that

pjur group Luxembourg S.A.

87, esplanade de la Moselle, 6637 Wasserbillig, Luxembourg

Has introduced, applies, and maintains a management system at the sites listed on the following pages.

This management system has been audited and found to conform to the quality management systems standard

EN ISO 13485:2016

This certificate is valid for the scope of activities and products/services indicated on the following pages.

Place and date Hamburg, 2023-05-03

((DAkkS

Deutsche Akkreditierungsstelle D-ZM-19630-04-00 For the issuing office DNV MEDCERT GmbH Pilatuspool 2, 20355 Hamburg, Germany

Marcus Harder Director Certification

contact info@medcert.de

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Certificate no. 7250GB445230503 Place and date Hamburg 2023-05-03

Sites covered by this certificate

pjur group Luxembourg S.A., 87, esplanade de la Moselle, 6637 Wasserbillig, Luxembourg pjur group Luxembourg S.A., 84, esplanade de la Moselle, 6637 Wasserbillig, Luxembourg

Activities and products/services covered by this certificate

Design and development, manufacturing, final inspection and distribution of

Lubricants for alleviation of vaginal dryness and / or as accessories for use with condoms



EU-Declaration of Conformity

Acc. to Annex IV of the EU Medical Devices Regulation 2017/745 (MDR)

DC838 Rev. 2

We, legal manufacturer

pjur group Luxembourg S.A.

registered place of business:

87, Esplanade de la Moselle

6637 Wasserbillig Luxembourg

Single Registration Nr.: LU-MF-000000315

declare under our sole responsability, that

Following medical devices:	pjur personal lubricants
Basic-UDI-DI according to Part C of Annex VI:	0827160PG002LB
Medical Device class:	IIb (acc. to Annex VIII MDR)
Intended purpose:	Lubricants for alleviation of vaginal dryness and / or for use with condoms
GMDN-Code:	60412
EMDN-Code:	U0803

to which this declaration relates comply with all requirements of the EU Medical Devices Regulation 2017/745 (MDR) that are applicable.

Basis of this declaration:

 EU Quality Management Certificate based on the conformity assessment acc. to Annex IX Chapters I and III of the MDR.

Certificate No. 7250GB448230503 dated 03.05.2023, valid until 15.05.2027.

Conformity assessment body:

DNV MEDCERT GmbH

Notified Body · ID No. 0482 Pilatuspool 2 · 20355 Hamburg Germany

www.pjur.com



EU-Declaration of Conformity

Acc. to Annex IV of the EU Medical Devices Regulation 2017/745 (MDR)

DC838 Rev. 2

The above devices are medical devices as defined in Article 2(1) of the MDR and comply with the general safety and performance requirements set out in Annex I of the MDR.

The conformity has been assessed and found to comply by means of the above-mentioned conformity assessment procedure. The corresponding provisions of the MDR, the State of the Art and, if available, the common specifications have been complied with.

The declaration is valid from the date of signature.

Wasserbillig, 2023-05-25

Place, Date

Andrea Giebel

(PRRC, pjur group Luxembourg S.A)