EU Quality Management System Certificate

Certificate no.	Final Assessment Report no.	Effective date	Expiry date
7250GB448240806	7250AU11F	2024-08-06	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, Chapters I and III 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, 2024-08-06

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-096

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

Lorenz Runge
Director Certification Body

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact Medcert-Info@dnv.com

Certificate no.: 7250GB448240806
Place and date: Hamburg, 2024-08-06

Preceding certificate

Certificate no.	Issue date	Identification of changes
7250GB448230503	2023-05-03	Extension by class IIb, EMDN M9002

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.: 7250GB448240806
Place and date: Hamburg, 2024-08-06

Products covered by this certificate

Class IIb medical devices, excluding implantable non-WET*

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

Category	EMDN code	Medical devices/groups of medical devices
MDN 1213	M9002	Protective devices, lubricants and soothing devices (sprays, gels, fluids and creams)

Intended purpose

Personal lubricant to prevent anal fissures / Reduces the risk of the condom breaking / Suitable for use with condoms

* WET (well-established technology) devices are those exempted according to Article 52 (4 and 5) from the requirement of assessment of technical documentation for every device, e.g. sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors.

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.	Final assessment report no.	Effective date	Expiry date
7250GB445230503	7250AU09F	2023-05-03	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

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. 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

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)*