



DNV

# 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**

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



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

**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](mailto:info@medcert.de)

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820111 EN Rev. 4 2022.10.17

NOTIFIED BODY 0482: DNV MEDCERT GmbH (previously: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH)  
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, [www.med-cert.com](http://www.med-cert.com), [www.dnv.com](http://www.dnv.com)



**DNV**

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



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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
<b>Intended purpose</b>		
Lubricants for alleviation of vaginal dryness and / or as accessories for use with condoms		



DNV

# 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

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](mailto:info@medcert.de)

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

820115 EN Rev 1 2022.10.17

ACCREDITED UNIT: MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH (currently registered as DNV MEDCERT GmbH)  
Pilatuspool 2, 20355 Hamburg, Germany, Tel +49 40 2263325-0, [www.med-cert.com](http://www.med-cert.com), [www.dnv.com](http://www.dnv.com)



**DNV**

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

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 responsibility, that

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

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. <sup>®</sup>

<p><b>Wasserbillig,</b> 2023-05-25</p>	
<p><i>Place, Date</i></p>	<p><b>Andrea Giebel</b> (PRRC, pjur group Luxembourg S.A)</p>