EU DECLARATION OF CONFORMITY

FPOCRD-012/03
Edition: 06
Issue date: December 11th, 2025
Revision date: December 2026

Manufacturers Name:	Oculus Technologies of México S.A. de C.V.
Manufacturers Address:	Industria Vidriera No. 81. Industrial Zapopan Norte Zip Code 45130 Zapopan, Jalisco, Mexico.
SRN:	MX-MF-000013827
Authorized Representative Name:	Sonoma Pharmaceuticals Netherlands B.V.
Authorized Representative Address:	Boven de Wolfskuil 3, C30-C32 6049 LX Herten/Roermond The Netherlands
SRN:	NL-AR-000013244
Notified Body Name:	Centro Nacional de Certificación de Productos Sanitarios
Notified Body Address:	C/ Campezo, 1 – Edificio 7 28022 Madrid, Spain
Notified Body Identification Number:	0318
Conformity Assessment Route:	Conformity assessment according to Annex IX, Chapter I and III, of Regulation (EU) 2017/745

Hereby we declare that the distributed CE marked products, specified in the attached product list, conform to the type(s) covered by the EU Quality Management System Certificate, no. **2024 CR 0031 Rev. 03**, issued on **August 12th, 2025**, by The Centro Nacional de Certificación de Productos Sanitarios, Notified Body Identification Number 0318, in accordance with the requirements established in the Annex IX of the "Medical Devices Regulation", Regulation (EU) 2017/745 of the European Parliament and the council of April 2017 on medical devices.

This EU Declaration of Conformity is based on the application of the approved Quality Management System for the design and development, manufacturing, shipping and customer service of the products concerned, in accordance with Annex IX of the Medical Device Regulation. The Quality Management System compliance set out in Annex IX is described in the EU Quality Management System Certificate no. **2024 CR 0031**, first issued on **July 10th 2024** by The Centro Nacional de Certificación de Productos Sanitarios.

This EU declaration of conformity is issued under the sole responsibility of Oculus Technologies of México S.A. de C.V. We hereby declare that the medical device(s) specified, and falling within Class IIa and Class IIb, meet the provision of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

This EU declaration of conformity is supported by the Quality Management System certification approved for the design and development, manufacturing, transportation, and customer service based on the harmonized standards ISO 13485:2016, Quality Management System Certificate with reference number: GSC13485MX129 dated December 11th, 2025, by Global Standards Certification.

The references to the relevant harmonized standards used or references to the specifications in relation to which conformity is declared:

- ISO 13485:2016
- ISO 14971:2019
- ISO 9001:2015

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The products that are part of the scope of this Declaration of Conformity are:

- **Class IIb**

MDN 1204: Non-active non-implantable devices for wound and skin care		
Product name	**B-UDI-DI**	**Intended purpose**
Microdacyn60 Wound Care	750227399WCS001CU	Electrolyzed solution intended for use in debridement and moisturizing wounds
Microdacyn60 Hydrogel	750227399WCH001AF	Electrolyzed solution intended for use in debridement and moisturizing wounds
Pediacyn	750227399DAH00122	Gel indicated as an adjuvant in the cicatrization process of wounds that can only heal by secondary intent, in the maturation phase. Indicated for the care of lesions associated with atopic dermatitis
Epicyn	750227399CIH0014D	Adjuvant in the cicatrization process of wounds that can only heal by secondary intent, in the maturation phase. Gel intended for the management and reduction of new and existing hypertrophic and keloid scars

MDN 1211: Non-active non-implantable devices for disinfecting, cleaning and rinsing.		
Product name	**B-UDI-DI**	**Intended purpose**
Microsafe	750227399DDS0015G	Electrolyzed solution intended for use in desinfection of semi-critical medical devices, such as endoscopes.

- **Clase IIa**

MD1204: Non-active non-implantable devices for wound and skin care	
Product name	**B-UDI DI**
Ocudox	750227399ECS0015J
GramaDerm Solution	750227399ACS0013W
GramaDerm Hydrogel	750227399ACH001ZE

MDN 1211: Non active non-implantable devices for disinfecting, cleaning and rinsing.	
Product name	**B-UDI DI**
Nanocyn	750227399DDS0025J

Trademarks, product part number, UDI-DI are found in Attachment I to the Declaration of Conformity.

All supporting documentation is retained at the premises of the manufacturer.

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Name	Position	Signature	Date
María Alejandra Robledo Zambrano	Person Responsible for Regulatory Compliance / Quality Assurance Director		December 11th, 2025
Everardo Orozco López	Plant Director		December 11th, 2025
Everardo Garibay Ramírez	General Director		December 11th, 2025

Place: Zapopan, Jalisco. Mexico.

Document History		
Edition	**Modification date**	**Changes made**
06	11-dec-2025	-Issuance date of ISO 13485 Certificate is updated and the products that are part of the scope of this Declaration of Conformity are added. -Attachment I with trademarks, product part number and UDI-DI is separated from the Declaration of Conformity
05	03-sep-2025	The Annex to the Declaration of Conformity is restructured to tell apart certified products from trademarks.
04	13-aug-2025	EU Certificate 2024 CR 0031 is updated to Rev. 03 and the following products are added: Microsafe, Electromicyn and Nanocyn.

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Attachment I to EU Declaration of Conformity
FPOCRD-012/03

Basic UDI-DI: 750227399WCS001CU

Product Name	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Microdacyn$_{60}$® Wound Care	IIb Rule 4	Electrolyzed solution intended for use in debridement and moisturizing wounds	M040415	60 ml / 24 Bottles per box (Individual Box)	P-E1386T00	07503048693058
				100 ml / 12 Bottles per box (Individual Box)	P-E1387T00	07503048693065
				120 ml / 12 Bottles per box (Individual Box)	P-E1388T00	07503048693072
				236 ml/ 12 Bottles per box (Individual Box)	P-E1389T00	07503048693089
				250 ml / 12 Bottles per box (Individual Box)	P-E1390T00	07503048693096
				250 ml /12 Bottles per box (Individual Box) Dosing Insert	P-E1391T00	07503048693102
				350 ml / 12 Bottles per box (Individual Box)	P-E1392T00	07503048693119
				500 ml / 24 Bottles per box (Individual Box)	P-E1393T00	07503048693126
				500 ml / 6 Bottles per box (Individual Box)	P-E1394T00	07503048693133
				500 ml / 24 Bottles per box (Individual Box) with Sprayer	P-E1395T00	07503048693140
				500 ml / 24 Bottles per box hg	P-E1396T00	07503048693157
				990 ml / 6 Bottles per box	P-E1397T00	07503048693164
				990 ml / 6 Bottles per box ft	P-E1398T00	07503048693171
				1 L / 6 Bottles per box	P-E1399T00	07503048693188
				5 L / 4 Bottles per box	P-E1400T00	07503048693195

Trademarks of the Basic UDI-DI 750227399WCS001CU

Trademark	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
AdvaCyn® Wound Care	IIb Rule 4	Electrolyzed solution intended for use in debridement and moisturizing wounds	M040415	100 ml / 12 Bottles per box (Individual Box)	P-E1401T00	07503048693201
				120 ml / 12 Bottles per box (Individual Box)	P-E1402T00	07503048693218
				250 ml / 12 Bottles per box (Individual Box)	P-E1403T00	07503048693225
				500 ml / 24 Bottles per box (Individual Box)	P-E1404T00	07503048693232
				500 ml / 6 Bottles per box (Individual Box)	P-E1405T00	07503048693249
				500 ml / 24 Bottles per box (Individual Box) with Sprayer	P-E1406T00	07503048693256
				990 ml / 6 Bottles per box	P-E1407T00	07503048693263
				1 L / 6 Bottles per box	P-E1408T00	07503048693270
				5 L / 4 Bottles per box	P-E1409T00	07503048693287
MicrosafeCare™ Solution	IIb Rule 4	Electrolyzed solution intended for use in debridement and moisturizing wounds	M040415	100 ml / 12 Bottles per box (Individual Box)	P-E1410T00	07503048693294
				120 ml / 12 Bottles per box (Individual Box)	P-E1411T00	07503048693300
				250 ml / 12 Bottles per box (Individual Box))	P-E1412T00	07503048693317
				500 ml / 24 Bottles per box (Individual Box)	P-E1413T00	07503048693324
				500 ml / 6 Bottles per box (Individual Box)	P-E1414T00	07503048693331
				500 ml / 24 Bottles per box (Individual Box) with Sprayer	P-E1415T00	07503048693348
				990 ml / 6 Bottles per box	P-E1416T00	07503048693355
				1 L / 6 Bottles per box	P-E1417T00	07503048693362
				5 L / 4 Bottles per box	P-E1418T00	07503048693379

Attachment I to EU Declaration of Conformity

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Trademark	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Lasercyn™	IIb Rule 4	Electrolyzed solution intended for use in debridement and moisturizing wounds	M040415	60 ml / 24 Bottles per box (Individual Box)	P-E1419T00	07503048693386
				120 ml / 12 Bottles per box (Individual Box)	P-E1420T00	07503048693393
MicroSafe® Lady Cool Solution	IIb Rule 4	Electrolyzed solution intended for use in debridement and moisturizing wounds	M040415	120 ml / 12 Bottles per box (Individual Box)	P-E1421T00	07503048693409
				236 ml / 12 Bottles per box (Individual Box)	P-E1422T00	07503048693416
Dermacyn Wound Care	IIb Rule 4	Electrolyzed solution intended for use in debridement and moisturizing wounds	M040415	100 ml/ 12 Bottles per box (Individual Box)	P-E1423T00	07503048693423
				120 ml/ 12 Bottles per box (Individual Box)	P-E1424T00	07503048693430
				236 ml/ 12 Bottles per box (Individual Box)	P-E1425T00	07503048693447
				250 ml/ 12 Bottles per box (Individual Box)	P-E1426T00	07503048693454
				250 ml / 12 Bottles per box (Individual Box) with cap	P-E1427T00	07503048693461
				350 ml/12 Bottles per box (Individual Box)	P-E1428T00	07503048693478
				500 ml /24 Bottles per box (Individual Box) with Sprayer	P-E1429T00	07503048693485
				500 ml/ 6 Bottles per box (Individual Box)	P-E1430T00	07503048693492
				500 ml/ 24 Bottles per box (Individual Box)	P-E1431T00	07503048693508
				500 ml/24 Bottles per box	P-E1432T00	07503048693515
				990ml/ 6 Bottles per box	P-E1433T00	07503048693522
				990ml/ 6 Bottles per box ft	P-E1434T00	07503048693539
				1L/ 6 Bottles per box	P-E1435T00	07503048693546
				5L/ 4 Bottles per box	P-E1436T00	07503048693553
Dermabac Wound Care	IIb Rule 4	Electrolyzed solution intended for use in debridement and moisturizing wounds	M040415	100 ml / 12 Bottles per box (Individual Box)	P-E1437T00	07503048693560
				120 ml / 12 Bottles per box (Individual Box)	P-E1438T00	07503048693577
				250 ml / 12 Bottles per box (Individual Box)	P-E1439T00	07503048693584
				350 ml / 12 Bottles per box (Individual Box)	P-E1440T00	07503048693591
				500 ml / 24 Bottles per box (Individual Box)	P-E1441T00	07503048693607
				500 ml / 24 Bottles per box (Individual Box) with Sprayer	P-E1442T00	07503048693614
				990 ml / 6 Bottles per box	P-E1443T00	07503048693621
				1 L / 6 Bottles per box	P-E1444T00	07503048693638
				5 L / 4 Bottles per box	P-E1445T00	07503048693645
MucoClyns	IIb Rule 4	Electrolyzed solution intended for use in debridement and moisturizing wounds	M040415	60 ml / 24 Bottles per box (Individual Box)	P-E1534T00	07503048701517
				120 ml / 12 Bottles per box (Individual Box)	P-E1535T00	07503048701524
				500 ml / 24 Bottles per box (Individual Box)	P-E1536T00	07503048701531
				1 L / 6 Bottles per box	P-E1537T00	07503048701548
				5 L/ 4 Bottles per box	P-E1538T00	07503048701555

Attachment I to EU Declaration of Conformity
FPOCRD-012/03

Basic UDI-DI: 750227399WCH001AF

Product Name	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Microdacyn$_{60}$® Hydrogel	IIb Rule 4	Electrolyzed hydrogel intended for use in debridement and moisturizing wounds	M040415	60 g / 24 Bottles per box (Individual Box)	P-E1446T00	07503048693652
				100 g / 24 Bottles per box (Individual Box)	P-E1447T00	07503048693669
				120 g / 6 Bottles per box (Individual Box)	P-E1448T00	07503048693676
				236 g / 6 Bottles per box (Individual Box)	P-E1449T00	07503048693683
				250 g / 6 Bottles per box (Individual Box)	P-E1450T00	07503048693690
				400 g / 12 Bottles per box (Individual Box)	P-E1451T00	07503048693706
				400 g / 36 Jars per box	P-E1452T00	07503048693713

Trademarks of the Basic UDI-DI 750227399WCH001AF

Trademark	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
AdvaCyn® Hydrogel	IIb Rule 4	Electrolyzed hydrogel intended for use in debridement and moisturizing wounds	M040415	60 g / 24 Bottles per box (Individual Box)	P-E1453T00	07503048693720
				120 g / 6 Bottles per box (Individual Box)	P-E1454T00	07503048693737
				250 g / 6 Bottles per box (Individual Box)	P-E1455T00	07503048693744
				400 g / 12 Bottles per box (Individual Box)	P-E1456T00	07503048693751
MicrosafeCare™ Hydrogel	IIb Rule 4	Electrolyzed hydrogel intended for use in debridement and moisturizing wounds	M040415	60 g / 24 Bottles per box (Individual Box)	P-E1457T00	07503048693768
				120 g / 6 Bottles per box (Individual Box)	P-E1458T00	07503048693775
				250 g / 6 Bottles per box (Individual Box)	P-E1459T00	07503048693782
				400 g / 12 Bottles per box (Individual Box)	P-E1460T00	07503048693799
				400 g / 36 Jars per box	P-E1461T00	07503048693805
Lasercyn™ Hydrogel	IIb Rule 4	Electrolyzed hydrogel intended for use in debridement and moisturizing wounds	M040415	60 g / 24 Bottles per box (Individual Box)	P-E1462T00	07503048693812
				120 g / 6 Bottles per box (Individual Box)	P-E1463T00	07503048693829
MicroSafe® Baby Cool Hydrogel	IIb Rule 4	Electrolyzed hydrogel intended for use in debridement and moisturizing wounds	M040415	60 g / 24 Bottles per box (Individual Box)	P-E1464T00	07503048693836
				100 g / 24 Bottles per box (Individual Box)	P-E1465T00	07503048693843
				250 g / 6 Bottles per box (Individual Box)	P-E1466T00	07503048693850
				400 g / 12 Bottles per box (Individual Box)	P-E1467T00	07503048693867
MicroSafe® Foot Cool Hydrogel	IIb Rule 4	Electrolyzed hydrogel intended for use in debridement and moisturizing wounds	M040415	60 g / 24 Bottles per box (Individual Box)	P-E1470T00	07503048693898
				100 g / 24 Bottles per box (Individual Box)	P-E1471T00	07503048693904
				250 g / 6 Bottles per box (Individual Box)	P-E1472T00	07503048693911
				400 g / 12 Bottles per box (Individual Box)	P-E1473T00	07503048693928
MicroSafe® Lady Cool Hydrogel	IIb Rule 4	Electrolyzed hydrogel intended for use in debridement and moisturizing wounds	M040415	100 g / 24 Bottles per box (Individual Box)	P-E1468T00	07503048693874
				236 g / 6 Bottles per box (Individual Box)	P-E1469T00	07503048693881
Microcyn® Skin & Wound Hydrogel	IIb Rule 4	Electrolyzed hydrogel intended for use in debridement and moisturizing wounds	M040415	60 g / 24 Bottles per box (Individual Box)	P-E1474T00	07503048693935
				100 g / 24 Bottles per box (Individual Box)	P-E1475T00	07503048693942
				120 g / 6 Bottles per box (Individual Box)	P-E1476T00	07503048693959
				236 g / 6 Bottles per box (Individual Box)	P-E1477T00	07503048693966
				250 g / 6 Bottles per box (Individual Box)	P-E1478T00	07503048693973
				400 g / 12 Bottles per box (Individual Box)	P-E1479T00	07503048693980
				400 g / 36 Jars per box	P-E1480T00	07503048693997
Dermabac Hydrogel	IIb Rule 4	Electrolyzed hydrogel intended for use in debridement and moisturizing wounds	M040415	60 g / 24 Bottles per box (Individual Box)	P-E1481T00	07503048701005
				120 g / 6 Bottles per box (Individual Box)	P-E1482T00	07503048701012
				250 g / 6 Bottles per box (Individual Box)	P-E1483T00	07503048701029
				400 g / 12 Bottles per box (Individual Box)	P-E1484T00	07503048701036

Attachment I to EU Declaration of Conformity

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Basic UDI-DI: 750227399CIH0014D

Product Name	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Epicyn™	IIb Rule 4	Adjuvant in the cicatrization process of wounds that can only heal by secondary intent, in the maturation phase. Gel intended for the management and reduction of new and existing hypertrophic and keloid scars.	M040415	15 g / 24 Bottles per box (Individual Box)	P-E1352T00	07502273999690
				30 g / 24 Bottles per box (Individual Box)	P-E1353T00	07502273999706
				45 g / 24 Bottles per box (Individual Box) -	P-E1355T00	07502273999720
				45 g / 24 Bottles per box (Individual Box) S ES//PT	P-E1356T00	07502273999737
				45 g / 24 Bottles per box (Individual Box) ES//PT	P-E1357T00	07502273999744
				75 g / 12 Bottles per box (Individual Box)	P-E1358T00	07502273999751
				150 g / 24 Bottles per box (Individual Box)	P-E1359T00	07502273999768
				400 g / 24 Jars per box	P-E1360T00	07502273999775

Trademarks of the Basic UDI-DI 750227399CIH0014D

Trademark	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Celacyn	IIb Rule 4	Adjuvant in the cicatrization process of wounds that can only heal by secondary intent, in the maturation phase. Gel intended for the management and reduction of new and existing hypertrophic and keloid scars.	M040415	15 g / 24 Bottles per box (Individual Box)	P-E1361T00	07502273999782
				45 g / 24 Bottles per box (Individual Box)	P-E1362T00	07502273999799
				75 g / 12 Bottles per box (Individual Box)	P-E1363T00	07502273999805
				150 g / 24 Bottles per box (Individual Box)	P-E1364T00	07502273999812
				400 g / 24 Jars per box	P-E1365T00	07502273999829

Attachment I to EU Declaration of Conformity
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Basic UDI-DI: 750227399DAH00122

Product Name	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Pediacyn™	IIb Rule 4	Gel indicated as an adjuvant in the cicatrization process of wounds that can only heal by secondary intent, in the maturation phase. Indicated for the care of lesions associated with atopic dermatitis.	M040415	15 g / 24 Bottles per box (Individual Box)	P-E1498T00	07503048701173
				30 g / 24 Bottles per box (Individual Box)	P-E1499T00	07503048701180
				45 g / 24 Bottles per box (Individual Box) -	P-E1501T00	07503048701197
				75 g / 12 Bottles per box (Individual Box)	P-E1502T00	07503048701203
				90 g / 12 Bottles per box (Individual Box)	P-E1503T00	07503048701210
				120 g / 12 Bottles per box (Individual Box)	P-E1504T00	07503048701227
				150 g / 24 Bottles per box (Individual Box)	P-E1505T00	07503048701234
				400 g / 24 Jars per box	P-E1506T00	07503048701241

Trademarks of the Basic UDI-DI 750227399DAH00122

Trademark	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Alevicyn	IIb Rule 4	Gel indicated as an adjuvant in the cicatrization process of wounds that can only heal by secondary intent, in the maturation phase. Indicated for the care of lesions associated with atopic dermatitis.	M040415	15 g / 24 Bottles per box (Individual Box)	P-E1507T00	07503048701258
				45 g / 24 Bottles per box (Individual Box)	P-E1508T00	07503048701265
				75 g / 12 Bottles per box (Individual Box)	P-E1509T00	07503048701272
				150 g / 24 Bottles per box (Individual Box)	P-E1510T00	07503048701289
				400 g / 24 Jars per box	P-E1511T00	07503048701296
SebuDerm Topical Gel	IIb Rule 4	Gel indicated as an adjuvant in the cicatrization process of wounds that can only heal by secondary intent, in the maturation phase. Indicated for the care of lesions associated with atopic dermatitis.	M040415	30 g / 24 Bottles per box (Individual Box)	P-E1539T00	07503048701562
				150 g / 24 Bottles per box (Individual Box)	P-E1540T00	07503048701579

Attachment I to EU Declaration of Conformity
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Basic UDI-DI: 750227399DDS0015G

Product Name	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Microsafe™	IIb Rule 16	Electrolyzed solution intended for use in disinfection of semi-critical medical devices, such as endoscopes.	D030101	5 L / 4 Bottles per box	P-E1373T00	07502273999904

Trademarks of the Basic UDI-DI 750227399DDS0015G

Trademark	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Electromicyn$_{60}$®	IIb Rule 16	Electrolyzed solution intended for use in disinfection of semi-critical medical devices, such as endoscopes.	D030101	5 L / 4 Bottles per box	P-E1376T00	07502273999935

Basic UDI-DI: 750227399DDS0025J

Product Name	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Nanocyn®	IIa Rule 16	Electrolyzed solution with bactericidal, yeasticidal, virucidal and sporicidal activity intended for disinfection without mechanical action, of surfaces of non-invasive medical devices used in the healthcare field, such as anesthesia machines, respiratory therapy equipment, computed tomography equipment, magnetic resonance equipment and angiography equipment.	D030101	60 ml / 24 Bottles per box	P-E1581T00	07503048701968
				60 ml / 24 Bottles per box (Individual Box)	P-E1582T00	07503048701975
				120 ml / 24 Bottles per box	P-E1583T00	07503048701982
				120 ml / 24 Bottles per box (Individual Box)	P-E1584T00	07503048701999
				500 ml /24 Bottles per box (Individual Box) with Sprayer	P-E1585T00	07503055954005
				1 L / 6 Bottles per box	P-E1586T00	07503055954012

Attachment I to EU Declaration of Conformity
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Basic UDI-DI: 750227399ECS0015J

Product Name	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Ocudox™	IIa Rule 4	Electrolyzed solution intended to assist in the treatment and symptoms of blepharitis on the eyelid. Can be used to clean minor cuts and burns of the periocular skin.	Q020302	20 ml / 24 Bottles per box (Individual Box) ES/PT	P-E1377T00	07502273999942
				20 ml/ 24 Bottles per box (Individual Box) IT	P-E1378T00	07502273999959
				60 ml / 24 Bottles per box (Individual Box) ES//PT	P-E1379T00	07502273999966
				60 ml / 24 Bottles per box (Individual Box) IT	P-E1380T00	07502273999973
				60 ml / 24 Bottles per box (Individual Box)-	P-E1381T00	07502273999980
				120 ml / 24 Bottles per box (Individual Box)	P-E1382T00	07502273999997

Trademarks of the Basic UDI-DI 750227399ECS0015J

Trademark	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
Microdacyn$_{60}$ Eye Care	IIa Rule 4	Electrolyzed solution intended to assist in the treatment and symptoms of blepharitis on the eyelid. Can be used to clean minor cuts and burns of the periocular skin.	Q020302	20 ml/ 24 Bottles per box (Individual Box)	P-E1383T00	07503048693027
				60 ml/ 24 Bottles per box (Individual Box)	P-E1384T00	07503048693034
MicroSafe EyeLid Treatment	IIa Rule 4	Electrolyzed solution intended to assist in the treatment and symptoms of blepharitis on the eyelid. Can be used to clean minor cuts and burns of the periocular skin.	Q020302	120 ml/ 24 Bottles per box (Individual Box)	P-E1385T00	07503048693041

Attachment I to EU Declaration of Conformity

FPOCRD-012/03

Basic UDI-DI: 750227399ACS0013W

Product Name	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
GramaDerm™ Solution	IIa Rule 4	Dermatological cleanser solution intended to be used as an adjunct in the topical treatment of mild to moderate acne.	V9099	60 ml / 24 Bottles per box (Individual Box)	P-E1485T00	07503048701043
				100 ml / 12 Bottles per box (Individual Box)	P-E1486T00	07503048701050
				120 ml / 12 Bottles per box (Individual Box)	P-E1487T00	07503048701067
				250 ml / 12 Bottles per box (Individual Box)	P-E1488T00	07503048701074

Basic UDI-DI: 750227399ACH001ZE

Product Name	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
GramaDerm™ Hydrogel	IIa Rule 4	Dermatological cleanser hydrogel intended to be used as an adjunct in the topical treatment of mild to moderate acne.	V9099	60 g / 24 Bottles per box (Individual Box)	P-E1489T00	07503048701081
				100 g / 12 Bottles per box (Individual Box)	P-E1490T00	07503048701098
				120 g / 6 Bottles per box (Individual Box)	P-E1491T00	07503048701104
				250 g / 6 Bottles per box (Individual Box)	P-E1492T00	07503048701111
				400 g / 12 Bottles per box (Individual Box)	P-E1493T00	07503048701128

Trademarks of the Basic UDI-DI 750227399ACH001ZE

Trademark	Class and classification Rule	Intended Use	EMDN Code	Package Configuration	Product Part Number	UDI-DI
MicroSafe® Face Cool Hydrogel	IIa Rule 4	Dermatological cleanser hydrogel intended to be used as an adjunct in the topical treatment of mild to moderate acne.	V9099	60 g / 24 Bottles per box (Individual Box)	P-E1494T00	07503048701135
				100 g / 12 Bottles per box (Individual Box)	P-E1495T00	07503048701142
				250 g / 6 Bottles per box (Individual Box)	P-E1496T00	07503048701159
				400 g / 12 Bottles per box (Individual Box)	P-E1497T00	07503048701166

Attachment History	
Modification date	**Changes made**
11-dic-2025	New Attachment