

ANNEX I (27-Jan-2026)

DECLARACION CE DE CONFORMIDAD CE CONFORMITY DECLARATION

UNOLAB MANUFACTURING, S.L., at C/ De las Flores nº 6, 28970, Humanes de Madrid (Madrid), Spain, manufacturer of the medical device collected in the annex 1.

Declares that the Medical Devices described in this annex 1 are according to the European directive 93/42/EEC in the annex V and annex VII about Medical devices and all next modifications. This declaration is backed the Confirmation Letter CL 097355 0006 Rev. 00, emitted by TÜV SÜD Product Service GmbH (id. No. 0123) on 2024-04-03 Ridlerstrasse 65 – 80339 Munich – Germany.

This declaration is related to EC certificate nº G2 097355 0004 Rev. 02 of production quality assurance system, certificates on 2020/03/05 by the TUV SUD product service GmbH (id. No. 0123)

UNOLAB MANUFACTURING, S.L is exclusively responsible for this declaration of conformity.

This declaration is covering all the batches place on the market within the day of the validity of the Confirmation Letter the device refers to.

Signed and dated in Humanes de Madrid on January 27th 2026

Firmado por LOPEZ BESGA
BEATRIZ PILAR - ***6984**
el día 28/01/2026 con un
certificado emitido por AC
FNMT Usuarios

Sign:

Beatriz López Besga
Directora General.

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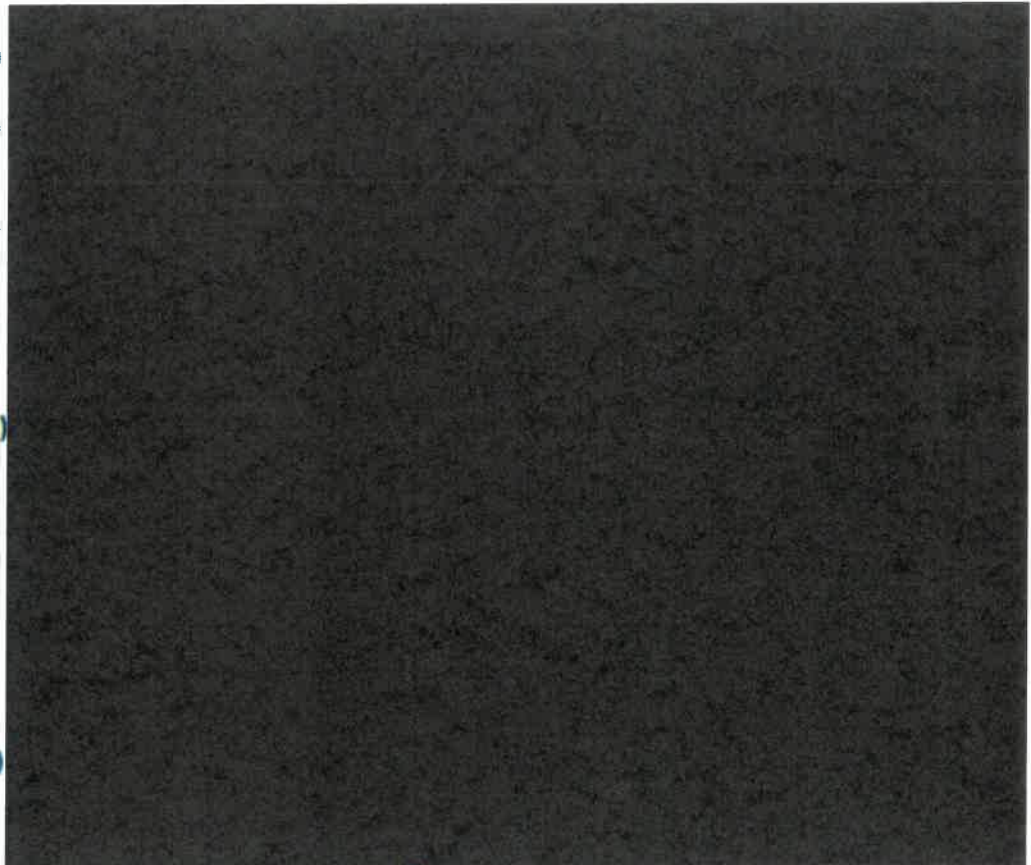
1. Solución Salina / Saline Solution 0,9%

Marca de Unolab / Brand of Unolab: Saline Solution 0,9% (Only for regulatory purpose)

1.1 Otras marcas /Other brands:

1.1.1 Variant 5 ml:

- a)
- b)
- c)
- d)
- e)
- f)
- g)
- h)
- i)
- j)
- k)
- l)
- m)
- n)
- o)
- p)
- q)
- r)
- s)
- t)
- u)
- v)
- w)
- x)
- y)
- z)



aa) PSU-0005 Elysium Steril Izotóniás Sóoldat 0,9% 20 x 5 mL

1.1.2 Variant 2.5 ml:

- a)
- b)
- c)
- d)
- e)
- f)
- g)
- h)
- i)



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j) SoFarmaplù Soluzione Isotonica 0,9% 20 X 2,5 mL

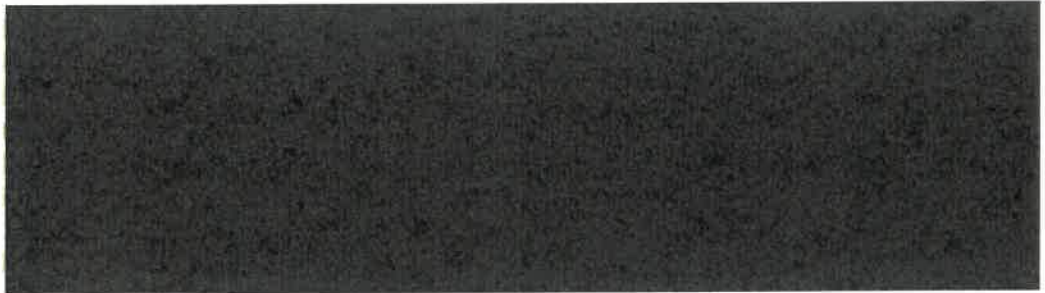
2. Solución Salina / Saline Solution 0,9% +HA

**Marca de Unolab / Brand of Unolab: Saline Solution 0,9% + HA
(Only for regulatory purpose)**

2.1 Otras marcas /Other brands:

- a)
- b)
- c)

- d)
- e)
- f)
- g)



3. Solución Salina / Saline Solution 3%

**Marca de Unolab / Brand of Unolab: Saline Solution 3% (Only for
regulatory purpose)**

3.1 Otras marcas / Other brands:

- a)
- b)
- c)
- d)
- e)
- f)
- g)
- h)
- i)
- j)
- k)
- l)
- m)
- n)
- o)



p) PSU-0006 Elysium Steril Hipertóniás Sóldat 3% 20 x 5 mL

4. Solución Salina / Saline Solution 3% +HA

**Marca de Unolab / Brand of Unolab: Saline Solution 3% + HA (Only
for regulatory purpose)**

4.1 Otras marcas / Other brands:

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- a)
- b)
- c)
- d)
- e)
- f)
- g)
- h)
- i)
- j)
- k)
- l)

m)

n)

o) PSU-0007 Elysium Steril Hipertóniás Sóoldat 3% + Hialuronsav
20 x 5 mL

5. Solución Salina / Saline Solution 5%

Marca de Unolab / Brand of Unolab: Saline Solution 5% (Only for regulatory purpose)

5.1 Otras marcas / Other brands:

XXXXX

6. Solución Salina / Saline Solution 7% +HA

Marca de Unolab / Brand of Unolab: Saline Solution 7% + HA (Only for regulatory purpose)

6.1 Otras marcas / Other brands:

- a)
- b)
- c)
- d)
- e)
- f)
- g)

h) PSU-0008 Elysium Steril Hipertóniás Sóoldat 7% + Hialuronsav
20 x 5 mL

7. Solución Salina / Saline Solution Nebu 0,9% +HA

Marca de Unolab / Brand of Unolab: Saline Solution Nebu 0,9% + HA (Only for regulatory purpose)

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7.1 Otras marcas / Other brands:

XXXXX

8. Solución Salina / Saline Solution Nebu 3% +HA

**Marca de Unolab / Brand of Unolab: Saline Solution Nebu 3% + HA
(Only for regulatory purpose)**

8.1 Otras marcas / Other brands:

XXXXX

9. Solución Salina / Saline Solution Nebu 7% +HA

**Marca de Unolab / Brand of Unolab: Saline Solution Nebu 7% + HA
(Only for regulatory purpose)**

9.1 Otras marcas / Other brands:

XXXXX

10. Solución Salina 1,5%/ Saline Solution 1.5%

**Marca de Unolab / Brand of Unolab Saline Solution 1.5% (Only for
regulatory purpose)**

10.1 Otras marcas / Other brands:

a)
b)
c)

**11. Solución Salina 0,9% + Ectoin +HA/ Saline Solution 0.9% + Ectoin
+HA**

**12. Marca de Unolab / Brand of Unolab Saline Solution 0.9% + Ectoin
+HA (Only for regulatory purpose)**

12.1 Otras marcas / Other brands:

a)
b)

**13. Solución Salina 3% + Ectoin / Saline Solution 3% + Ectoin
Marca de Unolab / Brand of Unolab Saline Solution 3% + Ectoin
(Only for regulatory purpose)**

13.1 Otras marcas / Other brands:

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- a)
- b)
- c)
- d)
- e)

