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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **B. Braun Medical AG, Seesatz 17, 6204 Sempach,** Authorisation No. 512428-102653076 with its site **B. Braun Medical AG, Route de Sorge 9, 1023 Crissier, Switzerland,** Site No. 1003530 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **01.10.2021** (dd.mm.yyyy).

No.	*Operation*	*Scope**
1	**MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)**	
1.1	**Sterile Products**	
1.1.2	Terminally sterilised (processing operations for the following dosage forms)	
1.1.2.1	Large volume liquids	H/V, I
1.1.2.3	Small volume liquids	H/V, I
1.1.3	Batch certification (technical release)	H/V, I
1.4	**Other products or manufacturing activity**	
1.4.2	Sterilisation of active substances / excipients / finished product	
1.4.2.3	Moist heat	H/V, I
1.5	**Packaging**	
1.5.1	Primary packaging	
1.5.1.5	Liquids for external use	H/V, I
1.5.1.6	Liquids for internal use	H/V, I
1.5.2	Secondary packaging	H/V, I
1.6	**Quality control testing**	
1.6.1	Microbiological: sterility	H/V, I
1.6.2	Microbiological: non-sterility	H/V, I
1.6.3	Chemical/Physical	H/V, I
1.6.4	Biological	H/V, I
3	**MANUFACTURE OF ACTIVE SUBSTANCES**	
3.1	**Manufacture of active substance by chemical synthesis**	
3.1.1	Manufacture of active substance intermediates	-
3.1.2	Manufacture of crude active substance	-

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No.	Operation	Scope*
3.5	**General finishing steps**	
3.5.2	Primary packaging	-
3.5.3	Secondary packaging	-
3.6	**Quality control testing**	
3.6.1	Physical / Chemical testing	-
3.6.2	Microbiological: testing (excluding sterility testing)	-
3.8	List of active substances: Hydroxyethyl Starch Succinylated Gelatin	-

* Scope of authorisation:
H/V Human and veterinary medicinal products, without investigational products
V Veterinary medicinal products only, without investigational products
I Human investigational medicinal products
– Not specified

Berne, **04.01.2022** (dd.mm.yyyy)
No. GMP-CH-1002873

Swiss Agency for Therapeutic Products swissmedic

Swissmedic, Swiss Agency for Therapeutic Products

E. Ehrensperger L.

Eva Ehrensperger Murri

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Acte en brevet
No 4'373

CERTIFIED TRUE COPY

I Claude Paquier, notary public for the canton de Vaud, at Chavannes-près-Renens (Switzerland), hereby certify that this document is a certified copy of the original document. ———————————————

Chavannes-près-Renens, the seventh of March two thousand and twenty-two. ———————————————

C. PAQUIER NOTAIRE

Claude Paquier, notary

qualified to practice in the State of Vaud, Switzerland

C. PAQUIER NOTAIRE

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Pays: SUISSE
País : SUIZO

Le présent acte public
El presente documento público

2. a été signé par Claude Paquier
ha sido firmado por

3. agissant en qualité de notaire à Chavannes-près-Renens
quien actúa en calidad de

4. est revêtu du sceau/timbre de C. PAQUIER * NOTAIRE
y está revestido del sello / timbre de

Attesté
Certificado

5. à Lausanne
en Lausana

6. le 29 avril 2022
el día

7. par la Chancellerie d'Etat du Canton de Vaud
por la Cancillería de Estado del Cantón de Vaud

8. sous N° 6'587
bajo el número

9. Sceau/timbre:
Sello / timbre :

CHANCELLERIE DU CONSEIL D'ÉTAT
CANTON DE VAUD
LIBERTÉ ET PATRIE

10. Signature:
Firma:

pr le Chancelier d'Etat:
para el canciller de estado :

Christophe CHEVALLEY