



CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **B. Braun Medical AG, Seesatz 17, 6204 Sempach**, Authorisation No. 512428-102695223 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/USA and Switzerland;

that from the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **17.11.2023** (dd.mm.yyyy), it is considered that it complies with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada/USA and Switzerland;

that this certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection.

The authenticity of this certificate may be verified in SwissGMDP/EudraGMDP. If it does not appear, please contact the issuing authority.

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

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

* 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

Bern, **29.01.2024** (dd.mm.yyyy)

No. GMP-CH-1005346

Swissmedic, Swiss Agency for Therapeutic Products.

SWISSGMDP