The Spanish Agency Of Medicines And Medical Devices

CERTIFICATE NUMBER:***ES/119HVI/21***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1) , (2)*

Part 1

Issued following an inspection in accordance with

The competent authority of Spain confirms the following:

The manufacturer: **B. BRAUN MEDICAL, S.A.**

Site address: **Ronda de Los Olivares, parcela 11, Polígono Industrial Los Olivares, Jaen, Jaén, 23009, Spain**

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***0041*** in accordance with Art. 13 of Directive 2001/20/EC, Art. 40 of Directive 2001/83/EC and Art. 44 of Directive 2001/82/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-11-03***, it is considered that it complies with:

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

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

(1) The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.
(2) Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.
(3) These requirements fulfil the GMP recommendations of WHO.

Part 2

1 MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)
1.1.1.4 Small volume liquids
Special Requirements :
7 Other: Other(en)
1.1.1.6 Other: [HV] Polvos estériles(en)
1.1.2 Terminally Sterilised (processing operations for the following dosage forms)
1.1.2.3 Small volume liquids
Special Requirements :
7 Other: Other(en)
1.1.3 Batch certification

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)
1.2.1.5 Liquids for external use
1.2.1.8 Other solid dosage forms
1.2.1.11 Semi-solids
Special Requirements :
7 Other: Other(en)
1.2.2 Batch certification

1.3 Biological medicinal products (list of product types)

1.3.1 Biological medicinal products (list of product types)
1.3.1.6 Human or animal extracted products
1.3.2 Batch Certification (list of product types)
1.3.2.6 Human or animal extracted products

1.5 Packaging

1.5.1 Primary Packaging
1.5.1.5 Liquids for external use
1.5.1.8 Other solid dosage forms
1.5.1.11 Semi-solids
1.5.2 Secondary packaging

1.6 Quality control testing

1.6.1 Microbiological: sterility
1.6.2 Microbiological: non-sterility
1.6.3 Chemical/Physical
1.6.4 Biological

2 IMPORTATION OF MEDICINAL PRODUCTS

2.2 Batch certification of imported medicinal products

2.2.1 Sterile products
2.2.1.1 Aseptically prepared

2.2.1.2 Terminally sterilised
2.2.2 Non-sterile products

Clarifying remarks (for public users):

[F/HV]Manufacture and storage of medicinal products with narcotic/psychotropic special requirements are authorised. 1.1.1.4, 1.1.2.3, 1.2.1.11 Others: Hormones or substances with hormonal activity 1.6.4: Bacterial endotoxin testing;

2021-08-02

Name and signature of the authorised person of the Competent Authority of

Confidential

Agencia Española de Medicamentos y Productos Sanitarios

Tel:***Confidential***

Fax:***Confidential***