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Competent Regional Authority *Direccion De Regulacion Planificacion Y Recursos Sanitarios Departamento De Salud Generalitat De Catalunya*

CERTIFICATE NUMBER: *NCF/2303/001/CAT*

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER⁽¹⁾ . ⁽²⁾

Part 1

Issued following an inspection in accordance with
Art. 94(1) of Regulation (EU) 2019/6 as amended
Art. 63 of Regulation (EU) 536/2014 as amended
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Spain confirms the following:
The manufacturer: **B BRAUN MEDICAL S.A.**
Site address: **Carretera Terrassa 121, Poligono Industrial Carretera De Terrassa, Rubi, 08191**
OMS Organisation Id. / OMS Location Id.: **ORG-100002344 / LOC-100004350**
Has been inspected under the national inspection programme in connection with manufacturing authorisation no. **0041** in accordance with Art. 88 of Regulation (EU) 2019/6, Art. 61 of Regulation (EU) No 536/2014 and Art. 40 of Directive 2001/83/EC.
Other
(Human) artículo 63, Real Decreto Legislativo 1/2015, de 24 de julio, Real Decreto 824/2010, de 25 de junio, Directiva 2003/94/CE, Directiva 91/412/CE

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2020-02-10**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 ⁽³⁾
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EC ⁽³⁾

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 Art. 80(5) of Directive 2001/82/EC, Art. 15 of Directive 2001/20/EC and Art. 111(5) of Directive 2001/83/EC is also applicable to importers.

(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

Veterinary Medicinal Products
Human Investigational Medicinal Products
Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.1 Sterile products

1.1.1 Aseptically prepared (processing operations for the following dosage forms)

1.1.1.6 Other: [HV] Preparados para nutrición parenteral/ Parenteral nutrition products(en)

1.1.2 Terminally Sterilised (processing operations for the following dosage forms)

1.1.2.1 Large volume liquids
1.1.2.3 Small volume liquids

1.1.3 Batch certification

1.5 Packaging

1.5.2 Secondary packaging

1.6 Quality control testing

1.6.1 Microbiological: 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

2.2.1.2 Terminally sterilised

Clarifying remarks (for public users):
[F/HV]1.1.2.1, 1.1.2.3: parametrically released is authorised where authorised by the marketing authorisations for each product.1.6.4: Bacterial endotoxin testingManufacture and storage of medicinal products with narcotic/psychotropic special requirements are

authorised 1.1.1.6 Manufacture of parenteral nutrition products() Authorisation issued in accordance with article 66.2 of the consolidated text of the Law of guarantees and rational use of medicines and medical devices approved by the Royal Legislative Decree 1/2015, of July 24th.; [F/I] 1.1.2.1, 1.1.2.3: parametrically released is authorised where authorised by the marketing authorisations for each product;*

2023-01-17

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

Confidential

Competent Regional Authority. Dirección de Regulación, Planificación y Recursos Sanitarios. Departamento de Salud. Generalitat de Catalunya

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Due to the restrictions caused by COVID-19, the period of validity of GMP and GDP certificates issued by EEA authorities is automatically extended until the end of 2024, except where clarifying remarks in the document state otherwise. Manufacturers, importers and distributors must continue to comply with GMP/GDP and all other legal obligations. On-site inspections are now being conducted and scheduling of these inspections may be independent of the extended validity period stated above. Competent authorities will continue to perform risk based supervision of sites by either on-site inspections or distant assessments and, based on the outcome, may continue to issue, withdraw or restrict GMP and GDP certificates, as appropriate.

For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

Documents issued by UK authorities up to and including 31 December 2020 remain available for consultation in EudraGMDP. However, they are no longer included or updated from 1 January 2021, with the exception of the documents pertaining to sites located in Northern Ireland.

As of 28 January 2022, the source of organisational data will change. Additional information and instructions are available on [EMA's website](#)

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