



Medicines & Healthcare products
Regulatory Agency

Mr Paul Bradley
B BRAUN MEDICAL LIMITED
THORNCLIFFE PARK
SHEFFIELD
SOUTH YORKSHIRE
S35 2PW
UNITED KINGDOM



MHRA
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E14 4PU
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gov.uk/mhra



MS NUMBER: MS 4296

Version: 16

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's "Specials" Licence

SECTION 1A

1. Licence Number

MS Number: MS 4296

2. Name of Licence Holder

B BRAUN MEDICAL LIMITED

3. Trading Style

4. Address(es) of manufacturing/importing site(s)

(All authorised sites should be listed if not covered by separate licences)

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
15286	B BRAUN MEDICAL LIMITED	UNIT 8, BROOKDALE ROAD, THORNCLIFFE PARK ESTATE, CHAPELTOWN, SHEFFIELD, S35 2PW, UNITED KINGDOM

5. Legally registered address of Licence Holder

THORNCLIFFE PARK, SHEFFIELD, SOUTH YORKSHIRE, S35 2PW, UNITED KINGDOM

6. Scope of authorisation and dosage form

See ANNEX 1

7. Legal basis of licence

See Section 1B of licence.

8. Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation



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SECTION 1A (continued)

9. Date 24/08/2026

10. Annexes attached

Annex 1

Optional Annexes

Annex 4 (Contract Laboratories)

Annex 5 (Name of Qualified Person)

Annex 6 (Name of Responsible Person)

Annex 8 (Manufactured/Imported products)

Annex 9 (Storage Sites)



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SECTION 1B

1. This licence is granted in accordance with Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916) and is subject to the provisions of these regulations.
2. It authorises the processes of manufacture and/or assembly and/or importation to which Regulation 167 of The Human Medicines Regulations 2012 (SI 2012/1916) applies, of the description or general classification at the premises specified and in accordance with the particulars set out in Section 3 by the licence holder named. All manufacturing operations in respect of those products for which a product licence is required shall be conducted so as to ensure that the products shall conform to the standards of strength, quality and purity applicable to them in accordance with the specification made by the person to whose order they are manufactured or the specification under which the products are sold or supplied.

In relation to such products the licence holder shall either:

- a) provide and maintain such staff, premises and plant as are necessary for carrying out in accordance with such specification any tests of the strength, quality or purity as required by that specification or,
 - b) make arrangements with a person approved by the Licensing Authority for such tests to be carried out on his behalf by that person.
3. The operations referred to in Section 3 shall be undertaken by the personnel named therein or by such other person as may be approved by the Licensing Authority.

Attention is drawn to the structure of this licence (as detailed on page 4 of Section 1) and to its completeness in accord with that structure. This is of particular relevance where the holder of the licence is using it as evidence to a third party in support of claims to carry out those operations and activities to which this licence applies on premises and using personnel covered by this licence.



SECTION 1B (continued)

4. The licence holder's arrangement for:

- a) identification and storage of materials and ingredients before and during manufacture and for the storage of medicinal products after manufacture or assembly;
- b) ensuring a satisfactory turnover of stock of medicinal products;
- c) maintaining records of production, of analytical and other testing procedures;
- d) keeping reference samples of materials used in the manufacture of any medicinal products shall be in accordance with the particulars contained in or furnished in connection with the application of this licence, or shall be in accordance with such other arrangements as may from time to time be approved by the Licensing Authority.

5. The licence holder must inform the Licensing Authority in advance of any change to the details submitted or included in this licence. All changes must be approved by the Licensing Authority prior to becoming effective. This includes any changes to named premises, persons, operations processes or structural alterations. If the business should change hands the new company or person must obtain a new licence prior to commencing operations.

6. A licence may be suspended if any fees are not paid in full as they fall due.

7. The Medicines and Healthcare products Regulatory Agency (MHRA) acts on behalf of the Licensing Authority established under The Human Medicines Regulations 2012 (SI 2012/1916).

8. Further information and specified guidelines may be obtained from the UK government website www.gov.uk/mhra.

9. Licence Structure

This Licence is divided into three sections.

- (a) Section 1 (this section) identifies the licence holder and holds the authorising signature for the issue of the licence. This section would not usually be replaced during routine variations of the licence unless the licence holder details are varied.
- (b) Section 2 lists variations to the licence. A replacement section 2 will be issued each time the licence is varied.
- (c) Section 3 contains the details relating to each site named on the licence. Where there is more than one site there will be more than one part to Section 3. When a variation is made to the details of a site named in Section 3 the relevant part of Section 3 will be replaced.
- (d) The licence holder is required to attach to his licence any replacement pages issued by MHRA and to mark or destroy superseded pages as to render them invalid.



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SECTION 2

VARIATION HISTORY

This page will be amended if the licence is varied.

Date	Variation Detail
18/01/2010	Initial Application
26/01/2010	Internal variation to add contract laboratory; International Laboratory Services Limited (Site 89192)
04/05/2012	Variation to site 15286, remove site contact Mr R Brookes, replace with Mrs H Milliband, replace Quality Controller Mrs H Milliband with C Cucuiu.
18/02/2013	Variation to site 15286: remove Mrs H Milliband as SC & Mr V Cucuiu as QC and add Mr L Grottick as SC & Mr P Mitchell as QC.
08/04/2013	Variation to replace Liam Grottick with Karen Jackson as the Licence Contact
25/06/2013	Variation: Site id 15286 change QC to Mr Rajan Pattni.
22/07/2013	Variation to add contact site, site id 2968688 Helvic Ltd, Trentham Business Quarter Unit E4, Bellringer Road, Stoke on Trent, Staffordshire, ST4 8GB to licence.
24/03/2014	Variation to amend authorisation holder contact and site contact for site 15286 to Mr Paul Bradley
08/12/2014	Variation to remove ILS Limited Laboratories. Site ID 89192
15/07/2015	Variation to site 15286 to replace Rajan with Adam rose as QC
22/11/2018	Variation: add Paul Bradley as Production Manager, remove Linda Abbot from the licence
05/07/2019	Variation to add site 91520 as a contract laboratory
19/10/2020	Variation to add Mr Kevin John Richardson as PM
16/12/2021	Variation to remove Mr Paul Bradley as PM and site contact. Remove Mr Kevin John Richardson as PM. Add Mr Peter Toland as PM. Remove site 2968688. Add site 23579643. Add Mr Adam Rose as site contact
08/12/2022	Variation replace Mr Peter Toland with Mr Ray Snell as PM
24/08/2026	Variation to replace Mr Ray Snell with Mr Jamie Wilson as PM. Remove third-party site 23579643



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SECTION 3

ANNEX 1 - SITE INFORMATION

SCOPE OF AUTHORISATION

NAME AND ADDRESS OF SITE:

SITE NAME:	B BRAUN MEDICAL LIMITED
ADDRESS:	UNIT 8, BROOKDALE ROAD, THORNCLIFFE PARK ESTATE, CHAPELTOWN, SHEFFIELD, S35 2PW, UNITED KINGDOM
MHRA SITE NUMBER:	15286

TYPE OF PRODUCTS HANDLED

Human Medicinal Products

AUTHORISED OPERATIONS

Manufacturing Operations (according to Part 1)	Authorised
Importation of Medicinal Products (according to Part 2)	Not Authorised



ANNEX 1 – SITE INFORMATION (continued)

Part 1 – MANUFACTURING OPERATIONS

- authorised manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, importation, storage and distribution of specified dosage forms unless informed to the contrary;
- quality control testing and/or release and batch certification activities without manufacturing operations should be specified under the relevant items;
- if the company is engaged in manufacture of products with special requirements e.g. radiopharmaceuticals or products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other or potentially hazardous active ingredients this should be stated under the relevant product type and dosage form (applicable to all sections of Part 1 apart from sections 1.5.2 and 1.6)

1.1	Sterile Products	Manufacture
1.1.1	Aseptically prepared (processing operations for the following dosage forms)	
	1.1.1.1 Large volume liquids	Authorised
	1.1.1.2 Lyophilisates	Not Authorised
	1.1.1.3 Semi-solids	Not Authorised
	1.1.1.4 Small volume liquids	Authorised
	1.1.1.5 Solids and implants	Not Authorised
	1.1.1.6 Other aseptically prepared products Large Volume Liquids and Small Volume Liquids include cytotoxics.	Authorised



1.1.2	<i>Terminally Sterilised (processing operations for the following dosage forms)</i>	Manufacture
	1.1.2.1 Large volume liquids	Not Authorised
	1.1.2.2 Semi-solids	Not Authorised
	1.1.2.3 Small volume liquids	Not Authorised
	1.1.2.4 Solids and implants	Not Authorised
	1.1.2.5 Other terminally sterilised prepared products	Not Authorised



1.2	Non-sterile products	Manufacture
1.2.1	<i>Non-Sterile Products (processing operations for the following dosage forms)</i>	
	1.2.1.1 Capsules, hard shell	Not Authorised
	1.2.1.2 Capsules, soft shell	Not Authorised
	1.2.1.3 Chewing gums	Not Authorised
	1.2.1.4 Impregnated matrices	Not Authorised
	1.2.1.5 Liquids for external use	Not Authorised
	1.2.1.6 Liquids for internal use	Not Authorised
	1.2.1.7 Medicinal gases	Not Authorised
	1.2.1.8 Other solid dosage forms	Not Authorised
	1.2.1.9 Pressurised preparations	Not Authorised
	1.2.1.10 Radionuclide generators	Not Authorised
	1.2.1.11 Semi-solids	Not Authorised
	1.2.1.12 Suppositories	Not Authorised
	1.2.1.13 Tablets	Not Authorised



	1.2.1.14 Transdermal patches	Not Authorised
	1.2.1.15 Other non-sterile medicinal products	Not Authorised



1.3	Biological medicinal products	Manufacture
1.3.1	<i>Biological medicinal products</i>	
	1.3.1.1 Blood products	Not Authorised
	1.3.1.2 Immunological products	Not Authorised
	1.3.1.3 Cell therapy products	Not Authorised
	1.3.1.4 Gene therapy products	Not Authorised
	1.3.1.5 Biotechnology products	Not Authorised
	1.3.1.6 Human or animal extracted products	Not Authorised
	1.3.1.7 Other biological medicinal products	Not Authorised



1.4	<i>Other products or manufacturing activity</i> (any other relevant manufacturing activity/product type that is not covered above e.g. sterilisation of active substances, manufacture of biological active starting materials (when required by national legislation), medicinal gases, herbal or homeopathic products, bulk or total manufacturing, etc).	Manufacture
1.4.1	Manufacture of:	
	1.4.1.1 Herbal products	Not Authorised
	1.4.1.2 Homoeopathic products	Not Authorised
	1.4.1.3 Biological active starting materials	Not Authorised
	1.4.1.4 Other	Not Authorised
1.4.2	Sterilisation of active substances/excipients/finished products:	
	1.4.2.1 Filtration	Not Authorised
	1.4.2.2 Dry heat	Not Authorised
	1.4.2.3 Moist heat	Not Authorised
	1.4.2.4 Chemical	Not Authorised
	1.4.2.5 Gamma irradiation	Not Authorised
	1.4.2.6 Electron beam	Not Authorised
1.4.3	Others	Not Authorised



1.5	Packaging	Manufacture
1.5.1	Primary packing	
	1.5.1.1 Capsules, hard shell	Not Authorised
	1.5.1.2 Capsules, soft shell	Not Authorised
	1.5.1.3 Chewing gums	Not Authorised
	1.5.1.4 Impregnated matrices	Not Authorised
	1.5.1.5 Liquids for external use	Not Authorised
	1.5.1.6 Liquids for internal use	Not Authorised
	1.5.1.7 Medicinal gases	Not Authorised
	1.5.1.8 Other solid dosage forms	Not Authorised
	1.5.1.9 Pressurised preparations	Not Authorised
	1.5.1.10 Radionuclide generators	Not Authorised
	1.5.1.11 Semi-solids	Not Authorised
	1.5.1.12 Suppositories	Not Authorised
	1.5.1.13 Tablets	Not Authorised
	1.5.1.14 Transdermal patches	Not Authorised
	1.5.1.15 Other non-sterile medicinal products	Not Authorised
1.5.2	Secondary packing	Not Authorised



1.6	Quality control testing	Manufacture
	1.6.1 Microbiological: sterility	Not Authorised
	1.6.2 Microbiological: non-sterility	Authorised
	1.6.3 Chemical/Physical	Authorised
	1.6.4 Biological	Not Authorised

Any restrictions or clarifying remarks related to the scope of these Manufacturing operations:



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ANNEX 5/6 – SITE INFORMATION (continued)

Personnel

<u>Person Number</u>	<u>Name</u>	<u>Personnel Type</u>	
		<u>PM</u>	<u>QC</u>
38991312	Mr Jamie Wilson	Yes	No
2750529	Adam Rose	No	Yes

Key to Roles:

PM – Production Manager/Supervisor

QC – Person responsible for Quality Control



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ANNEX 4 – CONTRACT LABORATORIES

MHRA SITE NUMBER:	LABORATORY NAME:	ADDRESS:
91520	QUALITY CONTROL NORTH WEST	PHARMACY PRACTICE UNIT, 70 PEMBROKE PLACE, LIVERPOOL, L69 3GF, UNITED KINGDOM



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ANNEX 9 – STORAGE SITES

MHRA SITE NUMBER:	SITE NAME:	ADDRESS:
15286	B BRAUN MEDICAL LIMITED	UNIT 8, BROOKDALE ROAD, THORNCLIFFE PARK ESTATE, CHAPELTOWN, SHEFFIELD, S35 2PW, UNITED KINGDOM