



Karen Jackson
B BRAUN MEDICAL LIMITED
UNIT 8
BROOKDALE ROAD
THORNCLIFFE PARK ESTATE
CHAPELTOWN
SHEFFIELD
S35 2PW
UNITED KINGDOM

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

gov.uk/mhra

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY On behalf of the Licensing Authority under The Human Medicines Regulations 2012

Wholesale Distribution Authorisation (Human)

- 1. This authorisation is granted in accordance with The Human Medicines Regulations 2012 and is subject to the provisions of those Regulations and the Medicines Act 1971.
- 2. This Wholesale Distribution Authorisation authorises distribution by way of wholesale dealing of medicinal products for human use by the authorisation holder named and storage of such products only on the premises located in the United Kingdom as specified.
- 3. The authorisation holder must provide and maintain such personnel, equipment and facilities as are necessary to avoid the deterioration of the medicinal products. If any change of premises is proposed prior approval must be sought from the Licensing Authority. Any proposals to make structural alterations to the premises must also be notified to the Licensing Authority.
- 4. The authorisation is not transferable to another legal entity.
- 5. The authorisation holder must not sell or supply a medicinal product, or offer it for sale or supply, unless:
 - there is an authorisation (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)
 - the sale or supply, or offer for sale or supply of the product is in accordance with the authorisation
 - the sale or supply of the medicinal is pursuant to an exemption from the requirements to hold such an authorisation (a special medicinal product), under the provisions of The Human Medicines Regulations 2012
 - the sale or supply of the medicinal product is pursuant to regulation 174 (supply in response to spread of pathogenic agents etc) under the provisions of The Human Medicines Regulations 2012
- 6. If authorised the authorisation holder must inform the Licensing Authority no later than 28 days prior to the import of a special medicinal from a listed approved country for import, stating the name of the medicinal product, any trademark or name of the manufacturer and their address, each active constituent, the quantity to be imported in accordance with the provision of The Human Medicines Regulations 2012. The authorisation holder must be able to demonstrate compliance with The Unlicensed Medicines Products for Human Use (Transmissible Spongiform Encephalopathies) (Safety) Regulations 2003 [SI 2003/1680].
- 7. If the intention is to import licensed medicinal products not from an approved country for import list an application for a manufacturer's licence that authorises import must be made and a licence granted for that purpose before commencing with this activity. Such a licence requires the holder to have available at all times a Qualified Person who must be named on the licence.
- 8. If the intention is to import a special medicinal product not from an approved country for import into the UK, an application for a manufacturer's "Specials" licence that authorises import must also be

made and a licence granted for that purpose before commencing with this activity. Such a licence requires only that a site contact be named, no Qualified Person is required.

- 9. If the intention is to carry out any manufacture and/or assembly processes (e.g. packing, filling or labelling) of medicinal products, an application for a manufacturer's licence must be made and a licence granted for that purpose before commencing with this activity.
- 10. This Wholesale Distribution Authorisation may be suspended if any fees are not paid in full as they fall due.
- 11. The Medicines and Healthcare Products Regulatory Agency (MHRA) acts on behalf of the Licensing Authority established under The Human Medicines Regulations 2012.
- 12. Further information and specified guidelines may be obtained from the UK government website www.gov.uk/mhra.
- 13. Authorisation Structure

This Wholesale Distribution Authorisation is divided into five annexes.

- (a) Annex 1: Scope of wholesale distribution authorisation
- (b) Annex 2: (Optional) Address(es) of contract wholesale distribution sites and their authorisation number
- (c) Annex 3: Name(s) of responsible person(s.)
- (d) Annex 4: Names(s) of the Responsible Person for import
- (e) Annex 5: Additional provisions based on national requirements

Attention is drawn to the structure of this authorisation and to its completeness in accordance with that structure. This is of particular relevance where the holder of the authorisation is using it as evidence to a third party in support of claims to carry out those operations and activities to which this authorisation applies on premises and using personnel covered by this authorisation.

- 14. Authorisation Holder
- (a) Authorisation Holder Number: WDA(H) 4296 has been granted to -

AUTHORISATION HOLDER:	B BRAUN MEDICAL LIMITED		
TRADING AS:			
ADDRESS:	UNIT 8, BROOKDALE ROAD, THORNCLIFFE PARK		
	ESTATE, CHAPELTOWN, SHEFFIELD, S35 2PW, UNITED		
	KINGDOM		
CONTACT NAME:	Karen Jackson		

- (b) This authorisation permits the authorisation holder to distribute by way of wholesale dealing medicinal products of the description or general classification specified, to be stored at the named premises on this authorisation.
- (c) This authorisation will continue to remain in force from the date of issue by the Licensing Authority unless cancelled, suspended, revoked or varied as to the period of its validity or relinquished by the authorisation holder.
- (d) Date granted 10/08/2022
- (e) Authorised by -

Name:	Asif Janjua
(A person a	uthorised to approve on behalf of the Secretary of State for Health.)
Date:	10/08/2022

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Wholesale Distribution Authorisation (Human)

VARIATION HISTORY

Date	Variation Detail	
01/01/1993		
15/04/1998	Renewal. Licence adds product category Wv (Veterinary & Merchant`s List/PML) so site is now for both veterinary and human medicines.	
22/01/1999	Change of LH/site details; add Wv & Wp.	
22/11/2000	Variation to replace RP Mr Smith with Mr Mitchell.	
29/10/2002	Variation to change communication address.	
16/04/2003	Renewal with changes to add category Ws and change the site contact to Mr P J Mitchell.	
05/09/2006	Variation to add UDG Site.	
28/05/2008	Variation to allow the handling of 'specials' and 'unlicensed' medicinal products.	
22/12/2009	Variation to add Cold Chain Products.	
22/02/2011	Variation to add additional site (Mawdsleys Brooks), add controlled drugs to site 15286, change the communications contact details to Mr Peter Mitchell, Brookdale Road, Thorncliffe Park Estate, Sheffield, S35 2PW and change the invoicing contact name to Ms Karen Jackson.	
14/10/2013	FMD update WL/WDL converted to WDA(H)	
27/05/2015	 Variation to change contact name from Peter Mitchell to Karen Jackson Variation to change RP from Peter Mitchell to Karen Jackson. Variation to change name of UDG (UNIDRUG DISTRIBUTION GROUP LIMITED) to: Alloga UK Ltd. (address to remain the same). 	
29/10/2018	Variation: - Add third party site: 3163392 - Mawdsley-Brooks & Company Ltd.	
22/11/2018	To add a third party site to WDA: 18394829 - Mawdsley Brooks & Company Limited	
28/06/2019	Variation application to add site 18630723. Also, confirmed site 15286 as the administration site.	
02/07/2019	Internal variation to amend site address for site 15286	
11/07/2019	Internal variation to add GSL medicinal product to Site 18630723	

13/12/2019	Variation to permit import of 1020 packs of Nutratain from Germany to meet UK public health needs, on a single occasion.
02/11/2020	Variation to permit import of 2800 packs of VIANT VIAL 5X5ML from Germany to meet UK public health needs, on a single occasion.
31/03/2021	Variation: - Add Ms Karen Jackson as a RPi - Add 2.6 & 2.6a to sites: 15286 & 18630723
18/07/2022	Variation to add Ms Sarah Wilson as RPi
10/08/2022	Variation to add site 15817048





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Wholesale Distribution Authorisation (Human)

Annex 4 - Name(s) of designated Responsible Person(s) for Import

Personnel

NAME:	ADDRESS:	
Mrs Sarah Wilson	UNIT 8, BROOKDALE ROAD, THORNCLIFFE PARK ESTATE, CHAPELTOWN, SHEFFIELD, S35 2PW, UNITED KINGDOM	
Karen Jackson	UNIT 8, BROOKDALE ROAD, THORNCLIFFE PARK ESTATE, CHAPELTOWN, SHEFFIELD, S35 2PW, UNITED KINGDOM	

Has/Have been designated the Responsible Person(s) for Import for WDA(H) 4296



WDA(H) Number: WDA(H) 4296 MHRA Site No: 18630723 Version: 12

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under The Human Medicines Regulations 2012

Wholesale Distribution Authorisation (Human)

Annex 1 - Scope of Wholesale Distribution Authorisation

The premises -

Site Name:	B BRAUN MEDICAL LIMITED		
Address:	UNIT 2, BROOKDALE ROAD, THORNCLIFFE PARK		
	ESTATE, CHAPELTOWN, SHEFFIELD, S35 2PW, UNITED		
	KINGDOM		
MHRA Site Number:	18630723		

is named on Authorisation Holder number: WDA(H) 4296 and authorised to perform the following:

- 1. Those operations as specified
- 2. Those descriptions of products or classes of product as specified
- 3. The personnel named to carry out the roles as specified

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





WDA(H) Number: WDA(H) 4296 MHRA Site No: 18630723 Version: 12

Annex 1 - Scope of Wholesale Distribution Authorisation (continued)

USE OF PRODUCTS AT SITE

1. MEDICINAL PRODUCTS

1.1 With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.2 Holding
- 2.3 Supply
- 2.6 Products imported from countries on a list
- 2.6a Products certified under Article 51 of Directive 2001/83/EC

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

Not Authorised





WDA(H) Number: WDA(H) 4296 MHRA Site No: 18630723 Version: 12

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Licensing Authority under The Human Medicines Regulations 2012

Wholesale Distribution Authorisation (Human)

Annex 5 - Additional Provisions Based on National Requirements

Site Name:	B BRAUN MEDICAL LIMITED		
Address:	UNIT 2, BROOKDALE ROAD, THORNCLIFFE PARK		
	ESTATE, CHAPELTOWN, SHEFFIELD, S35 2PW, UNITED		
	KINGDOM		
MHRA Site Number:	18630723		

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

- 4.1 Prescription Only Medicines
- 4.2 General Sales List
- 4.4 Pharmacy



WDA(H) Number: WDA(H) 4296 MHRA Site No: 15286 Version: 12

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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Wholesale Distribution Authorisation (Human)

Annex 1 - Scope of Wholesale Distribution Authorisation

The premises -

Site Name:	B BRAUN MEDICAL LIMITED		
Address:	UNIT 8, BROOKDALE ROAD, THORNCLIFFE PARK		
	ESTATE, CHAPELTOWN, SHEFFIELD, S35 2PW, UNITED		
	KINGDOM		
MHRA Site Number:	15286		

is named on Authorisation Holder number: WDA(H) 4296 and authorised to perform the following:

- 1. Those operations as specified
- 2. Those descriptions of products or classes of product as specified
- 3. The personnel named to carry out the roles as specified

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





WDA(H) Number: WDA(H) 4296 MHRA Site No: 15286 Version: 12

Annex 1 - Scope of Wholesale Distribution Authorisation (continued)

USE OF PRODUCTS AT SITE

1. MEDICINAL PRODUCTS

- 1.1 With "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)
- 1.2 Without "an authorisation" (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

- 2.1 Procurement
- 2.2 Holding
- 2.3 Supply
- 2.6 Products imported from countries on a list
- 2.6a Products certified under Article 51 of Directive 2001/83/EC

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

- 3.1.1 Narcotic or psychotropic products
- 3.3 Cold chain products (requiring low temperature handling)





WDA(H) Number: WDA(H) 4296 MHRA Site No: 15286 Version: 12

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Wholesale Distribution Authorisation (Human)

Annex 5 - Additional Provisions Based on National Requirements

Site Name:	B BRAUN MEDICAL LIMITED		
Address:	UNIT 8, BROOKDALE ROAD, THORNCLIFFE PARK		
	ESTATE, CHAPELTOWN, SHEFFIELD, S35 2PW, UNITED		
	KINGDOM		
MHRA Site Number:	15286		

4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE

- 4.1 Prescription Only Medicines
- 4.2 General Sales List
- 4.4 Pharmacy



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Wholesale Distribution Authorisation (Human)

Annex 2 - Address(es) of Contract Wholesale Distribution Sites and their Authorisation Number

Site Name	Address	Authorisation Holder Number	MHRA Site Number
MAWDSLEY- BROOKS &	QUEST 90, QUEST PARK, WHEATLEY HALL ROAD, DONCASTER, DN2 4LT,	WDA(H) 741	3163392
COMPANY LIMITED	UNITED KINGDOM		
THE TPS HEALTHCARE GROUP LIMITED	UNIT 200, WESTMINSTER 42, WESTMINSTER INDUSTRIAL ESTATE, REPTON ROAD, MEASHAM, SWADLINCOTE, DE12 7DT, UNITED KINGDOM	WDA(H) 8916	15817048
MAWDSLEYS (YORKSHIRE) LIMITED	PARKWAY DRIVE, UNIT 7, PARKWAY ONE BUSINESS CENTRE, SHEFFIELD, S9 4WU, UNITED KINGDOM	WDA(H) 741	91444
ALLOGA UK LIMITED	AMBER PARK 1, 2, AND 3, BERRISTOW LANE, SOUTH NORMANTON, ALFRETON, DE55 2FH, UNITED KINGDOM	WDA(H) 15694	6963
MAWDSLEY- BROOKS & COMPANY LIMITED	ROCKINGHAM WAY, REDHOUSE INTERCHANGE, ADWICK-LE-STREET, DONCASTER, DN6 7FB, UNITED KINGDOM	WDA(H) 741	18394829



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Wholesale Distribution Authorisation (Human)

Annex 3 - Name(s) of designated Responsible Person(s)

Personnel

Responsible Person			
Person Number	<u>Name</u>	<u>Site</u>	<u>Role</u>
1229788	Karen Jackson	18630723	Responsible Person
1229788	Karen Jackson	15286	Responsible Person