

**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**  
On behalf of the Licensing Authority under The Human Medicines Regulations  
2012 (SI 2012/1916)

## **Wholesale Distribution Authorisation (Human)**

---

1. This authorisation is granted in accordance with regulation 18 of The Human Medicines Regulations 2012 (SI 2012/1916) 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 a marketing authorisation, Article 126a authorisation, certificate of registration or traditional herbal registration (an "authorisation") in force in relation to the product
  - 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 (SI 2012/1916).
6. The authorisation holder must inform the Licensing Authority no later than 28 days prior to the sourcing from the EEA of a special medicinal product, 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 (SI 2012/1916). The authorisation holder must be able to demonstrate compliance with the European Commission 'Notes for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products' and future updates, in accordance 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 from outside the EEA 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 from outside the EEA 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 (SI 2012/1916).
12. Further information and specified guidelines may be obtained from the MHRA website ([www.mhra.gov.uk](http://www.mhra.gov.uk)).
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: (Optional) Date of Inspection on which authorisation was granted
- (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) 44056 has been granted to –

<b>AUTHORISATION HOLDER:</b>	B.N.O.S. MEDITECH LIMITED
<b>TRADING AS:</b>	
<b>ADDRESS:</b>	UNIT 9, FIFTH AVENUE, BLUEBRIDGE INDUSTRIAL ESTATE, HALSTEAD, CO9 2SZ, UNITED KINGDOM
<b>CONTACT NAME:</b>	Mr Christopher Buckenham

(b) This authorisation permits the authorisation holder to distribute by way of wholesale dealing within the EEA 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 - 26/02/2015

(e) Authorised by -

Name: Asif Janjua

(A person authorised to approve on behalf of the Secretary of State for Health.)

Date: 26/02/2015



**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**  
On behalf of the Licensing Authority under The Human Medicines Regulations  
2012 (SI 2012/1916)

**Wholesale Distribution Authorisation (Human)**

---

**VARIATION HISTORY**

<b>Date</b>	<b>Variation Detail</b>
23/02/2015	Initial application - B.N.O.S. MEDITECH LIMITED
26/02/2015	Internal variation to add medicinal gases to the licence



**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**  
On behalf of the Licensing Authority under The Human Medicines Regulations  
2012 (SI 2012/1916)

**Wholesale Distribution Authorisation (Human)**

---

**Annex 1 – Scope of Wholesale Distribution Authorisation**

The premises –

<b>Site Name:</b>	B.N.O.S. MEDITECH LIMITED
<b>Address:</b>	UNIT 9, FIFTH AVENUE, BLUEBRIDGE INDUSTRIAL ESTATE, HALSTEAD, CO9 2SZ, UNITED KINGDOM
<b>MHRA Site Number:</b>	11410101

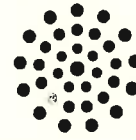
is named on Authorisation Holder number: WDA(H) 44056 and authorised to perform the following:

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

---





**Annex 1 - Scope of Wholesale Distribution Authorisation (continued)**

**USE OF PRODUCTS AT SITE**

**1. MEDICINAL PRODUCTS**

1.1 With a Marketing Authorisation in EEA member state(s)

**2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS**

2.1 Procurement

2.2 Holding

2.3 Supply

2.4 Export

**3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

**3.1 Products according to Art 83 of 2001/83/EC**

Not Authorised

3.2 Medicinal gases

3.3 Cold chain products (requiring low temperature handling)





**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**

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

**Wholesale Distribution Authorisation (Human)**

---

**Annex 5 – Additional Provisions Based on National Requirements**

<b>Site Name:</b>	B.N.O.S. MEDITECH LIMITED
<b>Address:</b>	UNIT 9, FIFTH AVENUE, BLUEBRIDGE INDUSTRIAL ESTATE, HALSTEAD, CO9 2SZ, UNITED KINGDOM
<b>MHRA Site Number:</b>	11410101

**4. CATEGORIES OF PRODUCTS HANDLED AT THIS SITE**

4.3 General Sales List Only





**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY**  
On behalf of the Licensing Authority under The Human Medicines Regulations  
2012 (SI 2012/1916)

**Wholesale Distribution Authorisation (Human)**

---

**Annex 3 – Name(s) of designated Responsible Person(s)**

**Personnel**

<b>Responsible Person</b>			
<b><u>Person Number</u></b>	<b><u>Name</u></b>	<b><u>Site</u></b>	<b><u>Role</u></b>
12362167	Mr Christopher Buckenham	11410101	Responsible Person





# Medicines and Healthcare products Regulatory Agency

Certificate No: UK WDA(H) 44056 Insp GDP 44056/11410101-0002

## CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Regulation 331 (4) (b) of the Human Medicines Regulations 2012

**The wholesale distributor :** B.N.O.S. MEDITECH LIMITED

**Site address :** B.N.O.S. MEDITECH LIMITED, UNIT 9, FIFTH AVENUE, BLUEBRIDGE INDUSTRIAL ESTATE, HALSTEAD, CO9 2SZ, UNITED KINGDOM

Has been inspected under the national inspection programme in connection with authorisation number UK WDA(H) 44056 Insp GDP 44056/11410101-0002 in accordance with regulation 18 of the Human Medicines Regulations 2012

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 17/06/2016, it is considered that it complies with the principles of good distribution practice requirements referred to in regulation C17 of the Human Medicines Regulations 2012

This certificate reflects the status of the premises at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of that inspection. However this period of validity may be reduced using regulatory risk management principles, by an entry in the Restrictions or Clarifying Remarks field.

This certificate is valid only when presented with all pages.

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

20/06/2016	Name and signature of the authorised person of the Competent Authority of United Kingdom
	Confidential
	Medicines and Healthcare products Regulatory Agency
	Confidential