Bulgarian Drug Agency

UNION FORMAT FOR A WHOLESALE DISTRIBUTION AUTHORISATION

(MEDICINAL PRODUCTS FOR HUMAN USE)

1. Authorisation Number	:	BG/WDA/MP-0164
2. Name of Authorisation Holder	:	" НОВУС ТРЕЙДИНГ" ЕООД/"NOVUS TRADING" EOOD
3. Legally registered address of Authorisation Holder	:	район „Витоша", кв. „Манастирски ливади", ул. „Българска легия" № 28, офис 1 /, region Vitosha, distr. Manastirski livadi, 28 Bulgarska legia Str., office 1, ЕИК / UIC: 203250662, Гр. София / Sofia, община Столична/Municipality of Sofia, 1612, Bulgaria
4. Address(es) of Site(s)	:	region Vitosha, r.a.Manastirski livadi, Bulgarska legia Str., bl.28, Sofia, 1612, Bulgaria
5. Scope of authorisation (complete for each site under 4)	:	ANNEX 1
6. Legal basis of authorisation	:	Art.77(1) of Directive 2001/83/EC
7. Name of responsible officer of the competent authority of the member state granting the wholesaling authorisation	:	Confidential, Confidential
8. Signature	:	
9. Date	:	2020-02-19
10. Annexes attached	:	Annex 1 Scope of wholesale distribution authorisation Annex 2 (Optional) Address(es) of contract wholesale distribution sites and their authorisation number Annex 3 (Optional) Name(s) of responsible person(s)

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Annex 4 (Optional) Date of Inspection on which authorisation was granted

Annex 5 (Optional) Additional provisions based on national requirements

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ANNEX 1

SCOPE OF WHOLESALE DISTRIBUTION AUTHORISATION

Name and address of the site: " НОВУС ТРЕЙДИНГ"ЕООД/"NOVUS TRADING" EOOD, region Vitosha, r.a.Manastirski livadi, Bulgarska legia Str., bl.28, Sofia, 1612, Bulgaria

1. MEDICINAL PRODUCTS

1.1 with a Marketing Authorisation in EEA country(s)
1.3 without a Marketing Authorisation in the EEA and intended for exportation

2. AUTHORISED WHOLESALE DISTRIBUTION OPERATIONS

2.1 Procurement
2.2 Holding
2.3 Supply
2.4 Export
2.5 Other activities(s): реекспорт/reexport

3. MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS

3.1 Products according to Art. 83 of 2001/83/EC **
3.1.3 Immunological medicinal products
3.3 Cold chain products(requiring low temperature handling)

*Art 5 of Directive 2001/83/EC or Art 83 of Regulation EC/726/2004
**Without prejudice to further authorisations as may be required according to national legislation

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