

# Medicines and Healthcare products Regulatory Agency

## MANUFACTURER'S AUTHORISATION

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|---|--|
| <b>1: Authorisation Number</b>  | UK MIA 2021  |
| <b>2: Name of authorisation holder</b>  | FUCHS LUBRICANTS (UK) PLC  |
| <b>3: Address(es) of manufacturing site(s)</b>  | FUCHS LUBRICANTS (UK) PLC, HANLEY PLANT, NEW CENTURY STREET, HANLEY, STOKE-ON-TRENT, ST1 5HU, UNITED KINGDOM |
| <b>4: Legally registered address of authorisation holder</b>  | FUCHS LUBRICANTS (UK) PLC, HANLEY PLANT, NEW CENTURY STREET, HANLEY, STOKE-ON-TRENT, ST1 5HU, UNITED KINGDOM |
| <b>5: Scope of authorisation and dosage forms</b>   | ANNEX 1 and/ or ANNEX 2  |
| <b>6: Legal Basis of authorisation</b>  | Regulation 17 of The Human Medicines Regulations 2012 (SI 2012/1916)   |
| <b>7: Name of responsible officer of the competent authority of the member state granting the manufacturing authorisation</b> | Confidential   |
| <b>8: Authorisation Date</b>  | 28/07/2020   |
| <b>9: Annexes attached</b>  | Annex 1 and/or Annex 2   |

### SCOPE OF AUTHORISATION

#### Annex 1

Name and address of the site:

**FUCHS LUBRICANTS (UK) PLC**, HANLEY PLANT, NEW CENTURY STREET, HANLEY, STOKE-ON-TRENT, ST1 5HU, UNITED KINGDOM

|                          |
|--------------------------|
| Human Medicinal Products |
|--------------------------|

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|-----------------------|
| Authorised Operations |
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| MANUFACTURING OPERATIONS (according to part 1) |
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#### Part 1 - MANUFACTURING OPERATIONS

##### [ 1.2 ] Non-sterile products

[ 1.2.1 ] Non-Sterile Products (processing operations for the following dosage forms)

[ 1.2.1.6 ] Liquids for internal use

[ 1.2.1.11 ] Semi-solids

[ 1.2.1.17 ] Other non-sterile medicinal products

Liquid Mineral hydrocarbon SI 1073 1966. Soft paraffin - BP/EP: used as excipients, Liquid & Light L

[ 1.2.2 ] Batch certification

##### [ 1.6 ] Quality control testing

MHRA-GMDP

MHRA

MHRA-GMDP

MHRA