**SCOPE OF AUTHORISATION** (delete the sections that do not apply) **ANNEX 1** Name and address of the site:

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| Human Medicinal Products Veterinary Medicinal Products  |

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| AUTHORISED OPERATIONS  Manufacturing Operations (according to part 1)  Importation of Medicinal Products (according to part 2)  |

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| **Part 1 - MANUFACTURING OPERATIONS**  |
| **1.1**  | **Sterile products**  |
|   | *1.1.1 Aseptically prepared (processing operations for the following dosage forms)* 1.1.1.1 Large volume liquids 1.1.1.2 Lyophilisates 1.1.1.3Semi-solids 1.1.1.4 Small volume liquids 1.1.1.5 Solids and implants  |
| 1.1.1.6 Other aseptically prepared products < | free text | >  |
|   | *1.1.2 Terminally sterilised (processing operations for the following dosage forms)*1.1.2.1 Large volume liquids 1.1.2.2 Semi-solids 1.1.2.3 Small volume liquids 1.1.2.4 Solids and implants  |
| 1.1.2.5 Other terminally sterilised prepared products < | free text | >  |
|   | *1.1.3 Batch certification*  |

Union Format for Manufacturer’s10F,2Authorisation

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| **1.2**  | **Non-sterile products** |
|  | *1.2.1 Non-sterile products (processing operations for the following dosage forms)* 1.2.1.1 Capsules, hard shell 1.2.1.2 Capsules, soft shell 1.2.1.3 Chewing gums 1.2.1.4 Impregnated matrices 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.7 Medicinal gases 1.2.1.8 Other solid dosage forms 1.2.1.9 Pressurised preparations 1.2.1.10 Radionuclide generators 1.2.1.11 Semi-solids 1.2.1.12 Suppositories 1.2.1.13 Tablets 1.2.1.14 Transdermal patches 1.2.1.15 Intraruminal devices1.2.1.16 Veterinary premixes  |
| 1.2.1.17 Other non-sterile medicinal product < | free text  | >  |
|  | *1.2.2 Batch Certification*  |
| **1.3**  | **Biological medicinal products** |
|  | *1.3.1 Biological medicinal products (list of product types)* 1.3.1.1 Blood products 1.3.1.2 Immunological products 1.3.1.3 Cell therapy products 1.3.1.4 Gene therapy products 1.3.1.5 Biotechnology products 1.3.1.6 Human or animal extracted products 1.3.1.7 Tissue engineered products  |
| 1.3.1.8 Other biological medicinal products < | free text  | > |
|  | *1.3.2 Batch certification(list of product types)* 1.3.2.1 Blood products 1.3.2.2 Immunological products 1.3.2.3 Cell therapy products 1.3.2.4 Gene therapy products 1.3.2.5 Biotechnology products 1.3.2.6 Human or animal extracted products 1.3.2.7 Tissue engineered products  |
| 1.3.2.8 Other biological medicinal products < | free text  | > |
| **1.4**  | **Other products or manufacturing activity**  |
|  | *1.4.1 Manufacture of:* 1.4.1.1 Herbal products 1.4.1.2 Homoeopathic products  |
| 1.4.1.3 Other < | free text  | >  |
|  | *1.4.2 Sterilisation of active substances/excipients/finished product:* 1.4.2.1 Filtration 1.4.2.2 Dry heat 1.4.2.3 Moist heat 1.4.2.4 Chemical 1.4.2.5 Gamma irradiation 1.4.2.6 Electron beam  |
|  | *1.4.3 Other <free text>*  |
| **1.5**  | **Packaging**  |
|  | *1.5.1 Primary packing* 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.3 Chewing gums 1.5.1.4 Impregnated matrices 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.7 Medicinal gases 1.5.1.8 Other solid dosage forms 1.5.1.9 Pressurised preparations 1.5.1.10 Radionuclide generators 1.5.1.11 Semi-solids 1.5.1.12 Suppositories 1.5.1.13 Tablets 1.5.1.14 Transdermal patches 1.5.1.15 Intraruminal devices 1.5.1.16 Veterinary premixes  |
| 1.5.1.17 Other non-sterile medicinal products < | free text  | >  |
|  | *1.5.2 Secondary packing*  |
| **1.6**  | **Quality control testing** |
|  | *1.6.1 Microbiological: sterility*  |
|  | *1.6.2 Microbiological: non-sterility*  |
|  | *1.6.3 Chemical/Physical*  |
|  | *1.6.4 Biological*  |

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

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| **Part 2** - **IMPORTATION OF MEDICINAL PRODUCTS**   |
| **2.1**  | **Quality control testing of imported medicinal products**  |
|  | *2.1.1 Microbiological: sterility*  |
|  | *2.1.2 Microbiological: non-sterility*  |
|  | *2.1.3 Chemical/Physical*  |
|  | *2.1.4 Biological*  |
| **2.2**  | **Batch certification of imported medicinal products** |
|  | *2.2.1 Sterile Products* 2.2.1.1 Aseptically prepared 2.2.1.2 Terminally sterilised  |
|  | *2.2.2 Non-sterile products*  |
|  | *2.2.3 Biological medicinal products* 2.2.3.1 Blood products 2.2.3.2 Immunological products 2.2.3.3 Cell therapy products 2.2.3.4 Gene therapy products 2.2.3.5 Biotechnology products2.2.3.6 Human or animal extracted products 2.2.3.7 Tissue engineered products |
| 2.2.3.8 Other biological medicinal products < | free text  | > |
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| **2.3**  | **Other importation activities** (any other importation activity that is not covered above) |
|  | *2.3.1 Site of physical importation*  |
| *2.3.2 Importation of intermediate which undergoes further processing*  |
| *2.3.3 Biological active substance*  |
| *2.3.4 Other <free text>*  |

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

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