**Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC.**

*Confirmation no:*

*1. Name and address of site (including building number, where applicable):*

…………………………………………………………………………………………………

*2. Manufacturer's licence number(s):*

…………………………………………………………………………………………………

REGARDING THE MANUFACTURING PLANT UNDER (1) OF THE FOLLOWING ACTIVE

SUBSTANCE(S) EXPORTED TO THE EU FOR MEDICINAL PRODUCTS FOR HUMAN USE

|  |  |
| --- | --- |
| Active substance(s): | Activity(ies): |
|  |  |
|  |  |
|  |  |

HEREBY CONFIRMS THAT:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU.

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU;

and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

*Date of inspection of the plant under (1)*

……………………………

This written confirmation remains valid until

……………………………

The authenticity of this written confirmation may be verified with the issuing regulatory authority.

This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

*Name and function of responsible person*

*Signature Stamp of the authority and date*