ANVISA

BRAZILIAN HEALTH SURVEILLANCE AGENCY

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

Confirmation N°

1. Name and address of site:

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):

THE ISSUING REGULATORY AUTHORITY 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 (= GMP of WHO/ICH Q7);

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: to

This written confirmation remains valid until:

Certification published in Brazilian Official Journal:

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

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.

THAIS MESQUITA DO COUTO ARAUJO

General Manager of Inspection - Substitute

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Date: