Statens legemiddelverk
Norwegian Medicines Agency

TO WHOM IT MAY CONCERN

Your ref.:	Date:	Our ref.:	Office/Officer:
	30 January 2014	13/11077-10	Seksjon for forvaltning/ Anne Thomassen

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER[1,2] – PART I

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC the competent authority of Norway confirms the following:

Diatec Monoclonals AS
Forskningsparken Bygning A, nivå 0
Gaustadalléen 21
NO-0349 Oslo
Norway

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the Norwegian Act of 4 December 1992 on Medicinal Products etc.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 3 October 2013, it is considered that it complies the principles of GMP for active substances[3] referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

The certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMP. If it does not appear, please contact the issuing authority.

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[1] The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, is also applicable to importers.

[2] Guidance on the interpretation of this template can be found in the Help menu of EudraGMP database.

[3] These requirements fulfill the GMP recommendations of WHO

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER – PART II

Diatec Monoclonals AS, Forskningsparken Bygning A, nivå 0, Gaustadalléen 21, NO-0349 Oslo, Norway

Human Medicinal Products

3 MANUFACTURING OPERATIONS – ACTIVE SUBSTANCE Active Substance(s): Intermediate of API of monoclonal antibodies	
3.3	**Manufacture of active substance using biological processes**
	3.3.2 Cell Culture mammalian *3.3.3 Isolation/ Purification*
3.5	**General finishing steps**
	3.5.1 Physical processing steps: filtration to remove cell debris *3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)* *3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)*
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *3.6.4 Biological Testing*

Any restrictions or clarifying remarks related to the scope of this certificate: Yes/No

Yours sincerely
Norwegian Medicines Agency

Hilde Ringstad (by authority)
Director of Department

NORWEGIAN MEDICINES AGENCY 30-01-2014

Anne Thomassen
Advisor