



# Agenzia Italiana del Farmaco

## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Certificate N° IT /aAMP/10/2010

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of **Republic of Italy** confirms the following:

The manufacturer: **GENTIUM S.P.A.**

Site address: **VILLA GUARDIA (CO) - PIAZZA XX SETTEMBRE, 2**

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation: **D.L. n. 219 of 24<sup>th</sup> April 2006 art. 53**

From the knowledge gained during inspection of this manufacturer, that was conducted on 2<sup>th</sup> April 2009, it is considered that it complies with the Good Manufacturing Practice requirements referred to in the principles of GMP for active substance 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, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

### Manufacture of active substance. Name of substances subject to inspection:

Extraction from tissues, organs and fluids of animal origin:

DEFIBROTIDE  
EPARINA CALCICA  
EPARINA SODICA  
SULGLICOTIDE

Purification, quality control and batch release:

UROCHINASI

The site is also authorised to import from non-eu countries the following active substances:

UROCHINASI GREZZA

10<sup>th</sup> March 2010

Name and signature of the authorised person of the  
Competent Authority of Republic of Italy  
Dott. Renato Massimi  
AIFA – Manufacturing Authorization Unit

AIFA Italian Medicines Agency  
Manufacturing Authorization Unit  
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LPC  
GMP