

We undersign, Mr. JF BIEGUN, Director of Quality and Regulatory Affairs and Mrs. F.BIEGUN, President of the company:

X. NOV
6 avenue des usines
90000 BELFORT
FRANCE

warrant and declare that the medical device:

CINEOS® hip prosthesis system
Femoral stem / Modular head 10-12 or 12-14
Femoral head/cone at 5°42' - 12/14 or cone at 6° - 10/12

belongs to the class III and is consistent:

- In Annex II of Directive 93/42/EEC of 14 June 1993 amended by Directive 2007/47/EC of 5 September 2007
and
- The provisions of Title I, Book II, Part V of the Code of Public Health (Article R5211-1et seq.)

Made in Belfort January the 05th /2009

JF. BIEGUN

Quality and Regulatory Affairs Director

ORIGINAL



F. BIEGUN

President

PRODUCT DESCRIPTION

Device nature or function:
Femoral stems and modular heads for hip prosthesis

Codes GMDN: P38156, P33175, P34190, P33581

Trademark :
Cineos®

Manufacturer:
X.NOV
6 avenue des usines
90000 BELFORT
FRANCE

Class of the device :
III

Product range
See table attached

ORIGINAL

Device Master File Codification : H01 - H05 - H01-2

