

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:

KAPS® UNICOMPARTMENTAL KNEE PROSTHESIS SYSTEM

belongs to the class III and is consistent:
- In Annex II of Directive 93/42/EEC of 14 June 1993
and
- The provisions of Title I, Book II, Part V of the Code of Public Health (Article R5211-1et seq.)

Made in Belfort September, the 30th/2011

JF. BIEGUN

Quality and Regulatory Affairs Director



F. BIEGUN

President

PRODUCT DESCRIPTION

Device nature or function:
Unicompartmental knee prosthesis

GMDN code: P33369, P48068, P48069, P48070

Trademark :
KAPS®

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

Class of the device :
III

Product range
See table attached

Device Master File Codification : G01