

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

X.NOV MEDICAL TECHNOLOGY
Rue D'Airmont 7
PORRENTROY
2900
Switzerland

Holds Certificate Number: **MD 645172**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Design, manufacturing and distribution of sterile orthopedic implants and associated sterile and non-sterile ancillaries



For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 06/06/2016

Latest Revision Date: 06/06/2016

Effective Date: 06/06/2016

Expiry Date: 29/12/2018

Page: 1 of 1



...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

X.NOV SA
Les Guinnotes 2
14 Rue du Chêne Sec
HERICOURT
70400
France

Holds Certificate Number: **MD 645991**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Design and distribution of sterile orthopedic implants and associated sterile and non-sterile ancillaries



For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 06/06/2016

Latest Revision Date: 06/06/2016

Effective Date: 06/06/2016

Expiry Date: 29/12/2018

Page: 1 of 1



...making excellence a habit.™

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated [online](#).
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.



EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 645170
Issued To: X.NOV MEDICAL TECHNOLOGY
Rue D'Airmont 7
PORRENTROY
2900
Switzerland

In respect of:

Design, development and manufacture of sterile orthopaedic implants for total hip and knee arthroplasty, associated non-sterile trial implants, and sterile and non-sterile instruments connecting to active devices.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Frank Lee, EMEA Compliance & Risk Director

First Issued: **25 March 2017**

Date: **25 March 2017**

Expiry Date: **29 July 2019**

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.



EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 645170**
Date: **25 March 2017**
Issued To: **X.NOV MEDICAL TECHNOLOGY
Rue D'Airmont 7
PORRENTUUY
2900
Switzerland**

Date	Reference Number	Action
25 March 2017	8440060	First issue, transfer from another Notified Body

...making excellence a habit.™

Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.