



Lloyd's  
Register



## EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices  
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK  
Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

**Corin Limited**  
**The Corinium Centre,**  
**Cirencester, Gloucestershire GL7 1YJ**  
**United Kingdom**

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations. In addition for Class III products approval is subject to the continued compliance with the EC Design Examination Certificate(s) as listed on the attached schedule.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 0941409/B  
Original Approval: 08 December 1994  
Current Certificate: 01 December 2018  
Certificate Expiry: 30 November 2021

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

**EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM  
CERTIFICATE LRQ 0941409/B SCHEDULE**

**In accordance with the requirements of the Medical Devices Directive  
93/42/EEC and the Medical Devices Regulations 2002, UK Statutory  
Instrument 2002 No. 618**

**Corin Limited  
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United Kingdom**

**Class I Sterile**

CCL001 Multilok Devices

**Class Ila Products**

CA005	AMC Uniglide Instrument Set
CML049	Bipolar Instrument Set
CML056	Ctl & CTill Instrument Set
CML057	Cenator Total Hip System Instrument Set
CML058	Taper-Fit Hip System Instrument Set
CML060	RTK+Replicate/X-Act2 Femoral Instrumentation Set
CML074	C-Fit Instrument Set
CML101	Alphalok Cup Instrument Set
CML106	Metafix Total Hip System Instrument Set
CML107	Zenith Ankle Instrument Set
CML08	MiniHip Total Hip Instrument Set
CML109	Trinity Acetabular Cup System Instrument Set
CML111	Unity Instrument Set
CML112	TriFit TS Instrument Set
CCL005	Coriflo+ Orthopaedic Suction System
CFX076b	LARS Instrument Set
TF-03	Dynacup cup, Dynacup One-C cup and insert BioloX® delta Instrument System
TF-11	Acetabular reinforcement ring Instrument System
TF-12	Dual mobility acetabular cup Instrument System
TF-06	Meije Duo Stem Instrument System
TF-17	PLEOS Hip Instrument System
TF-04	HLS KneeTec Instrument System

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**Class IIa Products**

TF-08	HLS Noetos RH Instrument System
TF-05	KneeTec Deep Dish Instrument System
TF-13	KneeTec PFJ Instrument System
TF-18	PLEOS Knee Instrument System
TF-14	HLS Uni Evolution Instrument System
TF-15	U-KneeTec Instrument System
TF-07	HLS Noetos Instrument System
TF-01	Oceane+ Stem Instrument System
TF-02	LINEA Stem Instrument System
TF-09	HLS Noetos Revision Instrument System

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### Class IIb Products

CML004	Corin Endoprosthesis (Austin Moore & Thompson Stems)
CML104	Zenith Total Ankle Replacement System
CM033	Modular Endoprosthesis Heads
DD03	Cement Restrictors and Canal Occluders
TFIIb-01	Acetabular reinforcement ring + cortical and cancellous bone screw
TFIIb-06	Cement restrictor
TFIIb-05	NM Bipolar Head
DD T04	HLS Noetos RH: Femoral augment and screw Tibial augment and screw
TFIIb-04	HLS Uni Evolution
TFIIb-03	U-KneeTec
DD T15	LINEA Stem: keyed screw
DD09	AMC MKII Tibial Augmentation Blocks
DD T13	HLS Noetos Revision: Femoral augment and screw Tibial augment and screw
DD T08	Dynacup cup: Bottom screw plug Cancellous bone screw

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United Kingdom**

**Class III Products**

Dual mobility acetabular cup  
Oceane+ Stem  
LINEA Stem  
Meije Duo Stem  
Metafix Hip Stem  
Minihip Stem  
Uniglide Unicondylar Knee System  
Taper Fit Hip Stems  
Rotaglide + Total Knee System  
Modular Femoral Heads  
Tri-Fit Hip System  
Alpha-Fit Hip System  
Alpha Cera-Fit Hip System

**EC Design Examination Certificate**

0088/0941409/00403  
0088/0941409/00404  
0088/0941409/00405  
0088/0941409/00406  
0088/0941409/00282  
0088/0941409/00283  
0088/0941409/00294  
0088/0941409/00290  
0088/0941409/00293  
0088/0941409/00296  
0088/0941409/00297  
0088/0941409/00300  
0088/0941409/00301

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### Class III Products

AMC MK 2 Total Knee System  
Trinity Acetabular System  
Corinium Hip System  
Unity Total Knee System  
TriFit TS Hip Stem  
Ceramic Head BioloX®  
HLS Noetos RH  
Metal femoral heads  
KneeTec Deep Dish Knee  
HLS Noetos  
Dynacup cup, Dynacup One-C cup  
HLS Noetos Revision  
HLS KNEETEC postero-stabilized knee

### EC Design Examination Certificate

0088/0941409/00302  
0088/0941409/00310  
0088/0941409/00313  
0088/0941409/00330  
0088/0941409/00340  
0088/0941409/00395  
0088/0941409/00396  
0088/0941409/00397  
0088/0941409/00398  
0088/0941409/00399  
0088/0941409/00400  
0088/0941409/00401  
0088/0941409/00402

Schedule Issue: 01

Date of Schedule Issue: 01 December 2018

LRQA Notified Body Number 0088

  
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