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By Royal Charter

EC Design-Examination Certificate

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

No. **CE 644025**

Issued To: **EVOLUTIS SAS**
Avenue de la Libération
Briennon
42720
France

In respect of:

Rolflex UC
Rolflex Tonic UC
Rolflex Tonic PS

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-05-16** Date: **2019-05-16** Expiry Date: **2024-05-15**

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EC Design-Examination Certificate

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

No. **CE 644018**

Issued To: **EVOLUTIS SAS**
Avenue de la Libération
Briennon
42720
France

In respect of:

Cemented femoral stems and associated femoral heads

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-10-15** Date: **2019-08-23** Expiry Date: **2024-05-26**

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EC Design-Examination Certificate

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

COPIE

No. **CE 644020**

Issued To: **EVOLUTIS SAS**
Avenue de la Libération
Briennon
42720
France

In respect of:

Cementless femoral stems and femoral heads

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2018-12-07** Date: **2019-03-11** Expiry Date: **2023-12-06**

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EC Design-Examination Certificate

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

No. **CE 644021**

Issued To: **EVOLUTIS SAS**
Avenue de la Libération
Briennon
42720
France

In respect of:

Cemented Femoral PE cups
Cemented Dual Mobility cups
Dual Mobility mobile PE inserts

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-02-14** Date: **2019-08-27** Expiry Date: **2024-05-26**

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By Royal Charter

EC Design-Examination Certificate

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

COPIE

No. **CE 644023**

Issued To: **EVOLUTIS SAS**
Avenue de la Libération
Briennon
42720
France

In respect of:

Coated dual mobility acetabular cups and mobile inserts

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **2018-11-23** Date: **2019-03-11** Expiry Date: **2023-11-22**

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By Royal Charter

EC Design-Examination Certificate

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

No. **CE 644022**

Issued To: **EVOLUTIS SAS**
Avenue de la Libération
Briennon
42720
France

In respect of:

Cementless Cups and Inserts

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2019-04-12** Date: **2019-04-12** Expiry Date: **2024-04-11**

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

EVOLUTIS SAS
10 place des Tuiliers
Briennon
42720
France

Holds Certificate Number: **MD 644017**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacturing, distribution and sales of medical devices for surgical use such as articular and osteosynthesis prostheses and associated ancillaries.

Conception, fabrication et distribution de dispositifs médicaux à usage chirurgical tels que prothèses articulaires et d'ostéosynthèse et ancillaires associés.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2016-06-13
Effective Date: 2019-11-19
Latest Revision Date: 2019-11-14
Expiry Date: 2022-11-18

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EC Design-Examination Certificate

Supplementary Information to CE 681360

Issued To:

TEKNIMED SAS
8 rue du Corps Franc-Pommiès
Vic En Bigorre
65500
France

Reference	Designation
B01 401A	EVOCEM G1
B01 403A	EVOCEM G3

First Issued: **2017 -12-16**

Date: **2020-12-15**

Expiry Date: **2024 -12-14**

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Lloyd's Register

Current issue date:	23 December 2020	Original approval:
Expiry date:	22 December 2023	ISO 13485 - 30 January 2006
Certificate identity number:	10308414	
Certificate approval number:	LRQ4002796	

Certificate of Approval

This is to certify that the Management System of:

Covision Medical Technologies Ltd

Carlton In Lindrick, Lawn Road, Carlton Industrial Estate, Nr Worksop, S81 9LB, United Kingdom

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Product approval number: ISO 13485 – 4002796

The scope of this approval is applicable to:
Control of manufacture of sterile and non-sterile orthopaedic implants, external fixators and associated instruments and devices.

David Derrick

Area Operations Manager UK & Ireland

Issued by: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001

SZUTEST

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-1707501

Manufacturer: **COVISION MEDICAL TECHNOLOGIES LTD.**
Lawn Road, Carlton Industrial Estate, Carlton in Lindrick, Nottinghamshire, United Kingdom

Product(s): **Sterile and Non Sterile Orthopaedic and Spinal Implants**

Model(s):
1. Sterile St. Leger Neo Knee System
2. Sterile Superica Knee System
3. Sterile CRP Hip System
4. Sterile Paragon Hip Stem
5. Sterile Troy Cemented Hip System
6. Sterile Troy Cementless Total Hip System
7. Sterile Straight Stem Hip System
8. Non-Sterile Unilock Locking Plate & Screws
9. Non-Sterile Orion Adult Spine System
10. Sterile Bone Plugs and Distal Centralizers
11. Non-Sterile Unican and Unitrack Screws
12. Non-Sterile Cable with Sleeve

Reference Report No: MM0631-P004-R01, MM0631-P004-R02, MM0631-P005-R01

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

This EC certificate is valid till 2023-12-25.

Issue Date:	2017-03-16
Revision No.:	03 Rev.
Revision Date:	2019-08-08

Rukiye BALKAN
Deputy General Manager

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number: 2195-MED-1707501-D06

Manufacturer:	**COVISION MEDICAL TECHNOLOGIES LTD.** Lawn Road, Carlton Industrial Estate, Carlton in Lindrick, Nottinghamshire, United Kingdom
Product(s):	**Sterile Superica Knee System**
Model(s):	Product models were given on the second page.
Reference Report No:	MM0631-P004-R01, MM0631-P004-R02

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

This EC Design Examination certificate is valid till 2023-12-25.

Rukiye BALKAN
Deputy General Manager

Issue Date:	2017-10-18
Revision No.:	01 Recertification
Revision Date:	2018-12-26

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

This version of certificate has come into force on 23.03.2017. FR 2195-MED-1707501-D06 Rev.01

FR MED 39 R.04

SZUTEST

Certificate Number: 2195-MED-1707501-D06

Sterile Superica Knee System

1.Superica Knee Femoral Component Cemented

2. Superica Knee Tibial Component Cemented

3. Superica Knee Tibial Insert

4. Superica Knee Tibial Insert Highly Crosslink

5.Superica Patellar Component

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi Akif İnan Sok. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr