144954-19-07-17

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Ltd. (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Orteq Sports Medicine Ltd.

Headquarters: **Collingham House, 6-12 Gladstone Road, Wimbledon, London SW19 1QT, UK**

Scope:

Biodegradable devices and accessories for use in orthopaedic procedures

This certificate is valid only with the annexes, in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 164-CE-171108

Issue: 1
Issued: 17 July 2019
First issued: 17 July 2019
Start date of certified status: 17 July 2019

Valter PAPP, Dr.
General Manager

Expires:
25 May 2024

CE Certiso Ltd.
NB2409
Notified Body

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NB ID number: 2409

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Annex 1/1

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Meniscal Scaffold included Meniscal Ruler and disposable (single use) Meniscal Ruler Guide	Actifit® Lateral Meniscal Scaffold	The Actifit is an absorbable /biodegradable meniscal scaffold that is to repair the meniscus by means of providing a scaffold for natural osteosynthesis.	AL3508 – Actifit® Lateral Meniscal Scaffold	III*
	Actifit® Medial Meniscal Scaffold		AM4508 – Actifit® Medial Meniscal Scaffold	
Actifit® Ruler Pack	MRP103 – Actifit® Ruler Pack	The Actifit® Ruler Pack is intended for use in arthroscopic procedures as an accessory to the Actifit® Meniscal Scaffold, to facilitate the determination of the meniscal defect length and the sizing of Actifit® Meniscal Scaffold	Actifit® Ruler Pack MRP103	II.a

*In case of devices in Class III, this certificate independently does not authorize the manufacturer for the use of CE mark on the devices.

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