

EC Certificate - Full Quality Assurance System

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

No. **CE 683264**
Issued To: **TRx Orthopaedics Limited**
Unit 1 and 2, Astley Way
Astley Lane Industrial Estate
Swillington, Leeds,
LS26 8XT
United Kingdom

In respect of:

Design, Development and Manufacture of OrthoPure XT porcine derived tissue scaffold implants for reconstruction of knee ligaments.

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 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-05-28**

Date: **2020-10-02**

Expiry Date: **2024-05-26**

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Page 1 of 2

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.

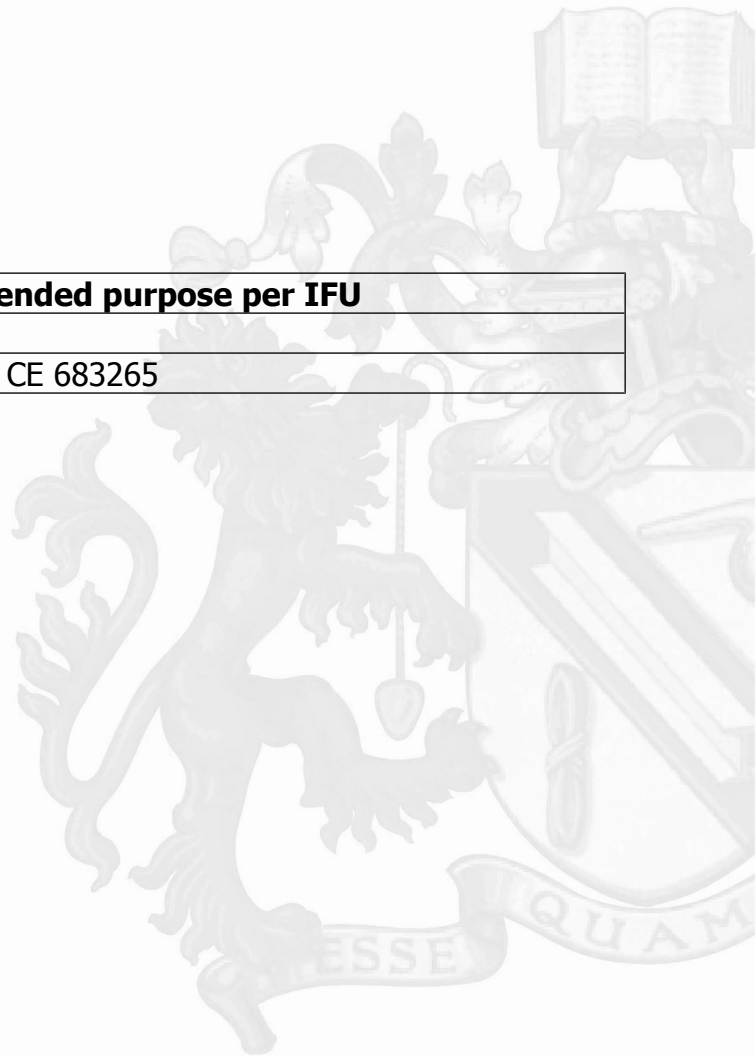
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Supplementary Information to CE 683264

Issued To:

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Number	Device Name	Intended purpose per IFU
Class III		
---	OrthoPure XT	See CE 683265



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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:

Service(s) supplied

Advena Ltd.
Tower Business Centre 2nd Flr.
Tower Street
Swatar BKR 4013
Malta

EU Representative

Karro Food Group
Hugden Way
Malton
North Yorkshire
YO17 GHG
United Kingdom

Animal Tissues / Derivatives

STERIS Applied Sterilization Technologies
Moray Road
Elgin Industrial Estate
Swindon
SN2 8XS
United Kingdom

Radiation (Gamma Sterilization)

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EC Certificate - Full Quality Assurance System Certificate History

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Date: 2020-10-02
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Certificate History

Date	Reference number	Action
28 May 2020	8855865	First Issue
Current	3278139	Addition of EU Representative "Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta."

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