By Royal Charter

UKCA Design-Examination Certificate

Part II of The Medical Devices Regulations 2002, Annex II Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 781107**

Issued To: **TRx Orthopaedics Limited**
Unite 3, Phoenix Court
Lotherton Way
Garforth
Leeds
LS25 2GY
United Kingdom

In respect of:

ORTHOPURE XT

BSI has performed a design examination of the above devices in accordance with Part II of The Medical Devices Regulations 2002, Annex II Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The design conforms to the requirements of this regulation. For the placing on the market of these products an Annex II (modified as described above) excluding Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2025-05-29** Date: **2025-05-29** Expiry Date: **2030-05-28**

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UKCA Design-Examination Certificate

Supplementary Information to UKCA 781107

Issued To:

TRx Orthopaedics Limited
Unite 3, Phoenix Court
Lotherton Way
Garforth
Leeds
LS25 2GY
United Kingdom

Intended Purpose as per the Instructions for Use:

OrthoPure XT is intended for reconstruction of knee ligaments to restore knee function and stability.

Classification: Class III

Catalogue Number	Device Name	Model, Type
2405XTS	OrthoPure XT size 5	Size 5 – A single tendon in a blister pack
2406XTS	OrthoPure XT size 6	Size 6 – A single tendon in a blister pack
2408XTD	OrthoPure XT size 8	Size 8 – Two single tendon in one blister pack
2410XTT	OrthoPure XT size 10	Size 10 – Three blister packs provided (a single tendon in each blister pack)

First Issued: **2025-05-29** Date: **2025-05-29** Expiry Date: **2030-05-28**

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Supplementary Information to UKCA 781107

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United Kingdom

Certificate History

Date	Reference Number	Action
Current	3755929	First Issue

First Issued: **2025-05-29** Date: **2025-05-29** Expiry Date: **2030-05-28**

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By Royal Charter

UKCA Certificate - Full Quality Assurance System

Part II of The Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

No. **UKCA 778282**

Issued To: **TRx Orthopaedics Limited**
Unite 3, Phoenix Court
Lotherton Way
Garforth
Leeds
LS25 2GY
United Kingdom

In respect of:

Design, manufacture and final inspection 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 Part II of the Medical Devices Regulations 2002, Annex II excluding Section 4 [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class III products an Annex II (modified as described above) Section 4 certificate is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2025-05-29** Date: **2025-05-29** Expiry Date: **2030-05-28**

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UKCA Certificate - Full Quality Assurance System

Supplementary Information to UKCA 778282

Issued To:

TRx Orthopaedics Limited
Unite 3, Phoenix Court
Lotherton Way
Garforth
Leeds
LS25 2GY
United Kingdom

Device code	Device name	Intended purpose per IFU
Class III		
---	OrthoPure XT	See UKCA 781107

First Issued: **2025-05-29** Date: **2025-05-29** Expiry Date: **2030-05-28**

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UKCA Certificate - Full Quality Assurance System Certificate History

Certificate No: **UKCA 778282**

Date: **2025-05-29**

Issued To: **TRx Orthopaedics Limited**
Unite 3, Phoenix Court
Lotherton Way
Garforth
Leeds
LS25 2GY
United Kingdom

Date	Reference Number	Action
Current	3754591	First issue

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