By Royal Charter

EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/745, Annex IX Chapter II

MDR 778429 R000

Manufacturer: TRx Orthopaedics Limited

Address:
Unit 3 Phoenix Court
Lotherton Way
Garforth
Leeds
LS25 2GY
United Kingdom

Single Registration Number: GB-MF-000018091

EU Authorised Representative: Advena Limited

Address:
Tower Business Centre, 2nd Flr
Tower Street
Swatar
BKR 4013
Malta

Scope: See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/745, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-05-29**

Current Issue Date: **2025-05-29**

Starting Validity Date: **2025-05-29**

Expiry Date: **2030-05-28**

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Device Schedule:

Intended Purpose as per the Instructions for Use:

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

Risk Classification: Class III, Implantable

Basic UDI-DI: 506026002XT001WA

Device Name	**Model**	**Type** (Codes as per (EU) 2017/2185)
OrthoPure XT size 5	2405XTS	MDN 1102
OrthoPure XT size 6	2406XTS	
OrthoPure XT size 8	2408XTD	
OrthoPure XT size 10	2410XTT	

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MDR 778429 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3755925	Issued

First Issue Date: **2025-05-29**

Current Issue Date: **2025-05-29**

Starting Validity Date: **2025-05-29**

Expiry Date: **2030-05-28**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 778283 R000

Manufacturer: TRx Orthopaedics Limited

Address:
Unit 3 Phoenix Court
Lotherton Way
Garforth
Leeds
LS25 2GY
United Kingdom

Single Registration Number: GB-MF-000018091

EU Authorised Representative: Advena Limited

Address:
Tower Business Centre, 2nd Flr
Tower Street
Swatar
BKR 4013
Malta

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

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

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-05-29**

Current Issue Date: **2025-05-29**

Starting Validity Date: **2025-05-29**

Expiry Date: **2030-05-28**

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EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 778283 R000

Device Schedule: Class III and Class IIb devices

Class III, Implantable	Intended purpose
OrthoPure XT	See MDR 778429

First Issue Date: **2025-05-29**

Current Issue Date: **2025-05-29**

Starting Validity Date: **2025-05-29**

Expiry Date: **2030-05-28**

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By Royal Charter

EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

MDR 778283 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3754594	Issued

First Issue Date: **2025-05-29**

Current Issue Date: **2025-05-29**

Starting Validity Date: **2025-05-29**

Expiry Date: **2030-05-28**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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