



Bussolengo (Verona), January 2nd, 2025

TO WHOM IT MAY CONCERN

ORTHOFIX S.R.L. a company organised and established in accordance with the Italian law, with registered office in Via Vittor Pisani n. 16, 20124 Milan, Italy, and principal place of business in Via delle Nazioni n. 9, 37012 Bussolengo (Verona), Italy

HEREBY CERTIFIES THAT

UAB OSTECA, with its principal office based in Danes g. 47, LT-92108, Klaipeda, LT, has been appointed as an exclusive distributor, effective as of **January 1st 2020**, to distribute in the territories of Latvia and Lithuania, according to the provisions of the Distribution Agreement in place with Orthofix S.r.l., and any and all subsequent amendments thereto.

The present letter is valid until December 31st, 2025.

Sincerely.

ORTHOFIX S.r.l.

CEO and Legal Representative

Bussolengo (Verona), 2025 m. sausio 2 d.

Tam, kam tai gali būti aktualu

ORTHOFIX S.R.L., įmonė, įsteigta ir valdoma pagal Italijos įstatymus, buveinės adresas Via Vittor Pisani Nr. 16, 20124 Milan, Italija, pagrindinės veiklos adresas Via delle Nazioni Nr. 9, 37012 Bussolengo (Verona), Italija

Šiuo raštu patvirtina, kad

UAB Ostecca, įsikūrusi Danės g. 47, LT-92108, Klaipėda, Lietuva, nuo 2020 m. sausio 1 dienos patvirtinta platintoja Lietuvos ir Latvijos teritorijose pagal platinimo sutarties su Orthofix S.r.l. nuostatas ir visus vėlesnius sutarties pakeitimus.

Šis įgaliojimas galioja iki 2025 m. gruodžio 31 d.

Pagarbiai

ORTHOFIX SRL

Paul W. Gonsalves

Generalinis direktorius ir teisinis atstovas



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 BS-MDR-099



Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
 (Class IIa and Class IIb Devices)

No. G10 052763 0027 Rev. 00

Manufacturer:

Orthofix S.r.l.

Via delle Nazioni, 9
 37012 Bussolengo - VR
 ITALY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10_052763_0027_Rev.00

Report No.: ITA1502855
Valid from: 2021-02-17
Valid until: 2025-11-26



Issue date: 2021-02-17

Head of Certification/Notified Body

