

EC Certificate - Full Quality Assurance System

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

No.**CE 641427**

Issued To:

**Tecres S.p.A.
Via Andrea Doria, 6
Sommacampagna (VR)
37066
Italy**

In respect of:

See certificate scope page.

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: **2016-08-10**Date: **2021-04-15**Expiry Date: **2024-05-26**

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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.

Certificate No: CE 641427

Certificate Scope:

The design and manufacture of medical devices listed below:

Bone cements

Bone cements with gentamicin;

Bone cements with gentamicin and vancomycin;

Spacers with gentamicin;

Spacers with gentamicin and vancomycin;

Acrylic Resin for Cranioplasty;

Bone void filler

Acrylic resins for spinal augmentation procedures (vertebroplasty, kyphoplasty) and screw augmentation

Bone cement accessories: Prep Kit with cement restrictors and Cement restrictors

Bone cement / Acrylic Resins / Bone Void Filler accessories: Prep Kit without cement restrictors, Femoral sponge, Femoral brush, Pressurizer, Curettes, Cannulae,

Mixing/Extrusion devices and Bone injection needles

Endorthesis screws

Trials for: spacers, endorthesis screws

Screws for rotator cuff repair procedures

Cemover and its accessory 8mm Drill

Kit for Kyphoplasty and other sites

Those aspects of Annex II related to the maintenance of sterility of medical devices listed below:

Bone cement / Acrylic Resins accessories: Bowl & Spatula, Cemex System Container,

Mixing/Extrusion/Delivery devices, Omomix-1, Freezer Ring, Manifold, Connection tubes, Mendec Aqua

Accessory for Kit for Kyphoplasty and other sites: Inflating Kit

Those aspects of Annex II concerned with the conformity of the products with the metrological requirements of the following medical devices:

Templates for Spacers

Accessory for Kit for Kyphoplasty and other sites: Inflating Kit.

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