

# EU Technical Documentation Assessment Certificate

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

## MDR 739363 R000

**Manufacturer:** Tecres S.p.A.

**Address:**

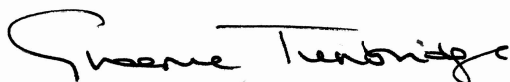
Via Andrea Doria, 6  
Sommacampagna (VR)  
37066  
Italy

**Single Registration Number:** IT-MF-000027512

**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 Medical Devices

First Issue Date: **2023-01-17**

Current Issue Date: **2023-01-17**

Starting Validity Date: **2023-01-17**

Expiry Date: **2028-01-16**

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### Intended Purpose as per the Instructions for Use:

VancoGenx-Space Hip is indicated for temporary use (maximum 180 days) in total hip replacement (THR) in skeletally mature patients undergoing a two-stage procedure due to a septic process

**Risk Classification:** Class III Implantable

**Basic UDI-DI:** 80314970212NF

**Type** (Codes as per (EU) 2017/2185): MDN 1102

### Device Schedule:

Ref. Code	Device Name	Model
SPC0030	VANCOGENX-SPACE HIP 46	Hip Spacer, 46mm head, standard stem
SPC0130	VANCOGENX-SPACE HIP 54	Hip Spacer, 54mm head, standard stem
SPC0230	VANCOGENX-SPACE HIP 60	Hip Spacer, 60mm head, standard stem
SPC0330	VANCOGENX-SPACE HIP 46XL	Hip Spacer, 46mm head, long stem
SPC0430	VANCOGENX-SPACE HIP 54XL	Hip Spacer, 54mm head, long stem
SPC0530	VANCOGENX-SPACE HIP 60XL	Hip Spacer, 60mm head, long stem
SPC0630	VANCOGENX-SPACE HIP FLAT STEM 46	Hip Spacer, 46mm head, standard flat stem
SPC0730	VANCOGENX-SPACE HIP FLAT STEM 54	Hip Spacer, 54mm head, standard flat stem
SPC0830	VANCOGENX-SPACE HIP FLAT STEM 60	Hip Spacer, 60mm head, standard flat stem
SPC0930	VANCOGENX-SPACE HIP FLAT STEM 46XL	Hip Spacer, 46mm head, long flat stem
SPC1030	VANCOGENX-SPACE HIP FLAT STEM 54XL	Hip Spacer, 54mm head, long flat stem
SPC1130	VANCOGENX-SPACE HIP FLAT STEM 60XL	Hip Spacer, 60mm head, long flat stem

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## 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](mailto:Certificate.Verification@bsigroup.com))*

Date	Reference Number	Action
Current	3325970	Issued

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