

## ***EC Declaration of Conformity***

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

**SRN:** IT-MF-000027512

**Basic UDI-DI:** 80314970212NF  
**Product name:** Vancogenx-Space Hip  
**Product codes and description:** see Annex 1

**Risk class:** III  
**Intended purpose** 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.

**Common Specification(s)** Not available

**Notified Body:** BSI Group The Netherlands B.V.  
NB 2797

**Conformity assessment route:** Annex IX Quality Management System Chapters I, III and Annex IX Chapter II Technical Documentation (paragraph 4 and paragraph 5, sub-paragraph 5.1, 5.2 and 5.3.2)

**EU Quality Management System Certificate**

Certificate Number	MDR 738034 R000
Issue Date	2021-05-10
Expiry Date	2026-05-09

**EU Technical Documentation Assessment Certificate**

Certificate Number	MDR 739363 R000
Issue Date	2023-01-17
Expiry Date	2028-01-16

This declaration of conformity is issued under the sole responsibility of the manufacturer. We hereby declare that the medical device(s) listed meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

All supporting documentation is retained at the premises of the manufacturer.

Place and date (yyyy-mm-dd) of issue:

Sommacampagna, 2023-01-19

Signature:

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Giuseppe Gazzara  
Technical Director

### **TECRES S.P.A.**

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T +39 045 9217311 - F +39 045 9217330 - [www.tecres.it](http://www.tecres.it)  
Cap.Soc. euro 850.000,00 i.v. - C.F. e Reg. Imprese VR 01346810235  
P.IVA 02042700233 - REA n° 211053 - Società a socio unico  
soggetta ad attività di direzione e coordinamento di Demetra Holding S.p.A.

## Annex 1

Ref. Code	Trade Name
SPC0030	VANCOGENX-SPACE HIP 46
SPC0130	VANCOGENX-SPACE HIP 54
SPC0230	VANCOGENX-SPACE HIP 60
SPC0330	VANCOGENX-SPACE HIP 46XL
SPC0430	VANCOGENX-SPACE HIP 54XL
SPC0530	VANCOGENX-SPACE HIP 60XL
SPC0630	VANCOGENX-SPACE HIP FLAT STEM 46
SPC0730	VANCOGENX-SPACE HIP FLAT STEM 54
SPC0830	VANCOGENX-SPACE HIP FLAT STEM 60
SPC0930	VANCOGENX-SPACE HIP FLAT STEM 46XL
SPC1030	VANCOGENX-SPACE HIP FLAT STEM 54XL
SPC1130	VANCOGENX-SPACE HIP FLAT STEM 60XL

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