

EU Technical Documentation Assessment Certificate

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

MDR 738108 R000

Manufacturer: Tecres S.p.A.

Address:

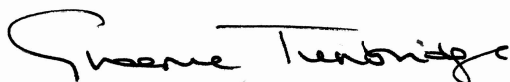
Via Andrea Doria, 6
Sommacampagna (VR)
37066
Italy

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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Device Schedule:

Intended Purpose as per the Instructions for Use:

Spacer-G 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: 80314970211ND

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

Ref. Code	Device Name	Model
SPC42/G	SPACER-G 42	Round stem profile – standard – diameter 42mm
SPC46/G	SPACER-G 46	Round stem profile – standard – diameter 46mm
SPC54/G	SPACER-G 54	Round stem profile – standard – diameter 54mm
SPC60/G	SPACER-G 60	Round stem profile – standard – diameter 60mm
SPC42/GXL	SPACER-G 42 XL	Round stem profile – long – diameter 42mm
SPC46/GXL	SPACER-G 46 XL	Round stem profile – long – diameter 46mm
SPC54/GXL	SPACER-G 54 XL	Round stem profile – long – diameter 54mm
SPC60/GXL	SPACER-G 60 XL	Round stem profile – long – diameter 60mm
SPC1220	SPACER-G FLAT 42	Rectangular stem profile – standard – diameter 42mm
SPC0620	SPACER-G FLAT 46	Rectangular stem profile – standard – diameter 46mm
SPC0720	SPACER-G FLAT 54	Rectangular stem profile – standard – diameter 54mm
SPC0820	SPACER-G FLAT 60	Rectangular stem profile – standard – diameter 60mm
SPC1420	SPACER-G FLAT 42 XL	Rectangular stem profile – long – diameter 42mm
SPC0920	SPACER-G FLAT 46 XL	Rectangular stem profile – long – diameter 46mm
SPC1020	SPACER-G FLAT 54 XL	Rectangular stem profile – long – diameter 54mm
SPC1120	SPACER-G FLAT 60 XL	Rectangular stem profile – long – diameter 60mm

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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)

Date	Reference Number	Action
Current	3311262	Issued

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