

EC Declaration of Conformity

Manufacturer:	Tecres S.p.A. Via Andrea Doria, 6 Sommacampagna (VR) 37066 Italy
SRN:	IT-MF-000027512
Basic UDI-DI:	80314970211ND
Product name:	Spacer-G
Product codes and description:	see Annex 1
Risk class:	III
Intended purpose	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.
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 738108 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.

TECRES S.P.A.

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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.



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

Sommacampagna, 2023-01-19

Signature:

.....
Giuseppe Gazzara
Technical Director

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Annex 1

Ref. Code	Trade Name
SPC42/G	SPACER-G 42
SPC46/G	SPACER-G 46
SPC54/G	SPACER-G 54
SPC60/G	SPACER-G 60
SPC42/GXL	SPACER-G 42 XL
SPC46/GXL	SPACER-G 46 XL
SPC54/GXL	SPACER-G 54 XL
SPC60/GXL	SPACER-G 60 XL
SPC1220	SPACER-G FLAT 42
SPC0620	SPACER-G FLAT 46
SPC0720	SPACER-G FLAT 54
SPC0820	SPACER-G FLAT 60
SPC1420	SPACER-G FLAT 42 XL
SPC0920	SPACER-G FLAT 46 XL
SPC1020	SPACER-G FLAT 54 XL
SPC1120	SPACER-G FLAT 60 XL

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