

EU Technical Documentation Assessment Certificate

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

MDR 738104 R000

Manufacturer: Tecres S.p.A.

Address:

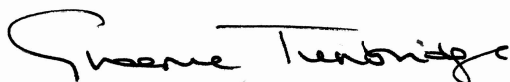
Via Andrea Doria, 6
Sommacampagna (VR)
37066
Italy

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 K and Spacer-K ATS is indicated for temporary use (maximum 180 days) in a total knee replacement (TKR) in skeletally mature patients undergoing a two-stage procedure due to a septic process.

Risk Classification: Class III Implantable

Basic UDI-DI: 80314970221NG

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

Ref. Code	Trade Name
SPK6054/G	Spacer-K 6054
SPK7064/G	Spacer-K 7064
SPK8074/G	Spacer-K 8074
SPK0420	Spacer-K ATS 60/07
SPK0520	Spacer-K ATS 60/12
SPK0620	Spacer-K ATS 80/07
SPK0720	Spacer-K ATS 80/12

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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	3311202	Issued

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