

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

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

**SRN:** IT-MF-000027512

**Basic UDI-DI:** 80314970221NG

**Product name:** Spacer-K

**Product codes and description:** see Annex 1

**Risk class:** III

**Intended purpose** Spacer-K is indicated for temporary use (maximum 180 days) in total knee replacement (TKR) 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 738104 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:

.....  
Giuseppe Gazzara  
Technical Director

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

Via Andrea Doria, 6 - 37066 Sommacampagna (VR) - Italy  
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
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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