

# Declaration of Conformity Certificate



**We, REGAL PROSTHESIS LTD., ensure and declare with sole responsibility, that our medical devices:**

UMDNS product group: **16096, “Prostheses, Joint, Knee, Total”**

Product code: **A1S, A2S, A2ZS, A3S, A4S, A5S, A5ZS, A6S, A7S, A8S, A8ZS, A10S, A11ZS, A12S, A12ZS, A22, T2A1S(210), T2A1S(410), T3S, 2N1S, 2SS, A1T, A2T, A2ZT, A3T, A4T, A5T, A5ZT, A6T, A7T, A8T, A8ZT, A10T, A11ZT, A12ZT, T2A1T(210), T2A1T(410), T3T, 2N1T, 2ST, B200, B400, BO200, BO400, BT200, BT400, BTO200, DA1, DB1, C300, C355, FA, FAC, FB, FBC, FBP, FKD, FT, FTT, KES8, TA1, TA4, TO1, TO2, TO4, UA1, 3020L, 3020C, BSL, LCL, TSL, TSL-S, TSL-T, P-A-S22, P-A-V1, P-A-V2, P-A-S14, P-MAT-PVA-0.065, P-MAT-PZ (3, 6, 12), P-MAT-PF (3, 4, 5, 6), P-MAT-STO-PER (9, 13, 18, 25), P-MAT-AKSTO, P-MAT-BKSTO, REG-OA-CM, REG-OA-CMH, REG-OA-PIG.**

**meet the provisions of Council Directive 93/42/EEC (MDD) which apply to them.**

Directive Classification : Class 1  
Intended use : Lower Limb Prosthesis Device  
Notified Body : None-Class 1 Devices  
Sterile : No  
Measuring Function . : No

We hereby appoint MDSS GmbH, Schiffgraben 41, 30175 Hannover, Germany to act as European Authorized Representative as defined in Article 1 (j) of the Medical Device Directive 93/42/EEC.

Date: 1 October 2008

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David Wong  
Manager

*An ISO 9001:2000 certified company  
Your reliable partner* ●●●



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