



CERTIFICATE



## EC Certificate

### Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-19-615

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

**Organization:**

### TEQUIR SL

Poligono Industrial El Oliveral, Calle C, S/N, 46190 Ribarroja del  
Turia, Valencia, SPAIN

**Product:** Femoral Implant "KEEP WALKING" and Surgical Instruments for the  
Femoral Implant "KEEP WALKING"

The products defined at the enclosure which is the part of this certificate and contains three page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

**Report Number:** M.5635.01

**Expiry Date:** 27 May 2024

Muhteşem Gökhan Yücel  
Head of Notified Body

11 September 2019, Istanbul, Turkey



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Enclosure of the EC Certificate:

Page 1/3

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Concerned medical devices;

Product: Femoral Implant "KEEP WALKING"

FEMORAL STEM REFERENCE	LENGTH, L (mm)	DIAMETER $\phi$ (mm)	FEMORAL STEM REFERENCE	LENGTH, L (mm)	DIAMETER $\phi$ (mm)
TGUI3111212	120	12	TGUI3111612	160	12
TGUI3111213	120	13	TGUI3111613	160	13
TGUI3111214	120	14	TGUI3111614	160	14
TGUI3111215	120	15	TGUI3111615	160	15
TGUI3111216	120	16	TGUI3111616	160	16
TGUI3111217	120	17	TGUI3111617	160	17
TGUI3111218	120	18	TGUI3111618	160	18
TGUI3111412	140	12	TGUI3111812	180	12
TGUI3111413	140	13	TGUI3111813	180	13
TGUI3111414	140	14	TGUI3111814	180	14
TGUI3111415	140	15	TGUI3111815	180	15
TGUI3111416	140	16	TGUI3111816	180	16
TGUI3111417	140	17	TGUI3111817	180	17
TGUI3111418	140	18	TGUI3111818	180	18

SPACER REFERENCE	SIZE	DIAMETER (mm)
TGUI3120054	SMALL	54
TGUI3120058	MEDIUM	58
TGUI3120062	LARGE	62

WASHER-SCREW ASSEMBLY REFERENCE	SIZE
TGUI3150000	UNIQUE

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Page 2/3

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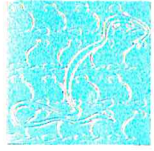
Concerned medical devices;

**Product:** Surgical Instruments for the Femoral Implant "KEEP WALKING"

Medular burr set		
REFERENCE	DESCRIPTION	DIAMETER $\phi$ (mm)
Medular burr		
TGUI0030112	Medular burr	12
TGUI0030113	Medular burr	13
TGUI0030114	Medular burr	14
TGUI0030115	Medular burr	15
TGUI0030116	Medular burr	16
TGUI0030117	Medular burr	17
TGUI0030118	Medular burr	18
TGUI0030300	Frontal plane burr	
TGUI0030500	Medular burr nut	

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Page 3/3

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**Product:** Surgical Instruments for the Femoral Implant "KEEP WALKING"

REFERENCE	DESCRIPTION	DIAMETER $\phi$ (mm)
<b>Conical burr set</b>		
TGUI0030212	Conical burr guide	12
TGUI0030213	Conical burr guide	13
TGUI0030214	Conical burr guide	14
TGUI0030215	Conical burr guide	15
TGUI0030216	Conical burr guide	16
TGUI0030217	Conical burr guide	17
TGUI0030218	Conical burr guide	18
TGUI0030220	Milling head	$\phi$ 12-17
TGUI0030221	Milling head	$\phi$ 18
<b>Conical burr stopper</b>		
TGUI0030231	Conical burr stopper	$\phi$ 12, 13, 14
TGUI0030232	Conical burr stopper	$\phi$ 15, 16, 17
TGUI0030233	Conical burr stopper	$\phi$ 18
TGUI0030250	Conical burr nut	

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

11 September 2019, Istanbul, Turkey

Muhteşem Gökhan Yücel  
Head of Notified Body