



CERTIFICATE



EC Certificate
Design Examination According to
Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-736

We hereby declare that a design examination has been carried out on the devices listed hereafter following the requirements of the national legislation to which the undersigned is subjected, transposing Annex II Section 4 of the Directive 93/42/EEC on medical devices. We certify that the design of the device(s) listed thereafter conforms with the relevant provisions of Annex II Section 4 of the Directive 93/42/EEC on medical devices as transposed into national legislation.

Organization

3S ORTHO

Les passerelles – 24 avenue Joannes Masset – 69009 Lyon - FRANCE

Product: ETIP-TF ARAMIS-T – Trauma shoulder prosthesis

The products defined at the enclosure which is the part of this certificate and contains one (1) page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Full quality assurance system according to Medical Devices Directive 93/42/EEC Annex-II Section 3 certificate is also mandatory for class III devices covered by this certificate.

Report Number: M.5771.01

Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

08 February 2021, Istanbul, Turkey



Enclosure of the EC Certificate:

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Design Examination

Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-21-736

Concerned medical devices;

Product: ARAMIS-T – Trauma shoulder prosthesis

Reference	Designation
ETI T008	Trauma humeral stem \varnothing 8.5mm
ETI T010	Trauma humeral stem \varnothing 10mm
ETI T011	Trauma humeral stem \varnothing 11.5mm
ETI V420	Locking screw \varnothing 4mm L20mm
ETI V422	Locking screw \varnothing 4mm L22mm
ETI V424	Locking screw \varnothing 4mm L24mm
ETI V426	Locking screw \varnothing 4mm L26mm
ETI V428	Locking screw \varnothing 4mm L28mm
ETI V430	Locking screw \varnothing 4mm L30mm
ETI V432	Locking screw \varnothing 4mm L32mm
ETI V434	Locking screw \varnothing 4mm L34mm
ETI V436	Locking screw \varnothing 4mm L36mm
ETI V438	Locking screw \varnothing 4mm L38mm
ETI V442	Locking screw \varnothing 4mm L42mm
ETI V446	Locking screw \varnothing 4mm L46mm
ETI V450	Locking screw \varnothing 4mm L50mm
ETI PLUG	Obturator plug – conical and oblong

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

08 February 2021, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body



CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-20-704

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:

3S ORTHO

Les passerelles – 24 avenue Joannes Masset – 69009 Lyon - FRANCE

Products:

ESI-TF ARAMIS-S – Stemless Shoulder Prosthesis (Class III),

EAI-TF ARAMIS – Total Shoulder Prosthesis (Class III),

MII-TF IPP2 – Proximal Interphalangeal Prosthesis (Class IIb),

MRI-TF RUBIS MODULAIRE – Trapeziometacarpal Prosthesis (Class IIb),

EAA-TF Instruments ARAMIS range – Reusable surgical instruments with a connection to an active device (Class IIa),

ETIP-TF ARAMIS-T – Trauma shoulder prosthesis (Class III),

ETIN-TF ARAMIS-T – Trauma humeral nail (Class IIb)

ERI-TF ARAMIS-R – Revision shoulder prosthesis (Class III)

The products defined at the enclosure which is the part of this certificate and contains eight (8) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III devices covered by this certificate.

Report Number: M.5771.01

Date of first issue: 07 September 2020

Date of last issue: 17 May 2021

Revision Number: 02

Expiry Date: 27 May 2024

Muhteşem Gökhan Yücel
Head of Notified Body

17 May 2021, Istanbul, Turkey



Enclosure of the EC Certificate:

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

Certificate Number: 1984-MDD-20-704, Revision Number: 02

Concerned medical devices;

Product: ARAMIS S-Stemless Shoulder Prosthesis

Reference	Designation
ESI 2122	Humeral base – Ø21 L22mm
ESI 2124	Humeral base – Ø21 L24mm
ESI 4014	Centered humeral head Ø40 H14mm
ESI 4315	Centered humeral head Ø43 H15mm
ESI 4617	Centered humeral head Ø46 H17mm
ESI 4918	Centered humeral head Ø49 H18mm
ESI 4920	Centered humeral head Ø49 H20mm

Product: ARAMIS-Total Shoulder Prosthesis

Reference	Designation
EAI 0H08	Cementless humeral stem Ø8.5mm / 132°
EAI 0H10	Cementless humeral stem Ø10mm / 132°
EAI 0H11	Cementless humeral stem Ø11.5mm / 132°
EAI 0H13	Cementless humeral stem Ø13mm / 132°
EAI 0C07	Cemented humeral stem Ø7mm / 132°
EAI 0C08	Cemented humeral stem Ø8.5mm / 132°
EAI 0C10	Cemented humeral stem Ø10mm / 132°
EAI 0C11	Cemented humeral stem Ø11.5mm / 132°
EAI 1H08	Cementless humeral stem Ø8.5mm / 140°
EAI 1H10	Cementless humeral stem Ø10mm / 140°
EAI 1H11	Cementless humeral stem Ø11.5mm / 140°
EAI 1H13	Cementless humeral stem Ø13mm / 140°
EAI 1C07	Cemented humeral stem Ø7mm / 140°
EAI 1C08	Cemented humeral stem Ø8.5mm / 140°

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

Certificate Number: 1984-MDD-20-704, Revision Number: 02

Concerned medical devices;

Product: ARAMIS-Total Shoulder Prosthesis

Reference	Designation
EAI 1C10	Cemented humeral stem \varnothing 10mm / 140°
EAI 1C11	Cemented humeral stem \varnothing 11.5mm / 140°
EAI 0E07	Cementless humeral short stem \varnothing 7mm / 132°
EAI 0E08	Cementless humeral short stem \varnothing 8,5mm / 132°
EAI 0E10	Cementless humeral short stem \varnothing 10mm / 132°
EAI 0E11	Cementless humeral short stem \varnothing 11,5mm / 132°
EAI 0E13	Cementless humeral short stem \varnothing 13mm / 132°
EAI 1E07	Cementless humeral short stem \varnothing 7mm / 140°
EAI 1E08	Cementless humeral short stem \varnothing 8,5mm / 140°
EAI 1E10	Cementless humeral short stem \varnothing 10mm / 140°
EAI 1E11	Cementless humeral short stem \varnothing 11,5mm / 140°
EAI 1E13	Cementless humeral short stem \varnothing 13mm / 140°
EAI 4013	Humeral off-centered head \varnothing 40 H13mm
EAI 4315	Humeral off-centered head \varnothing 43 H15mm
EAI 4617	Humeral off-centered head \varnothing 46 H17mm
EAI 4918	Humeral off-centered head \varnothing 49 H18mm
EAI 4920	Humeral off-centered head \varnothing 49 H20mm
EAI G030	Glenoid \varnothing 30mm
EAI G033	Glenoid \varnothing 33mm
EAI G036	Glenoid \varnothing 36mm
EAI G136	Glenoid \varnothing 36mm R34
EAI CHC0	Humeral cup - centered 0°
EAI CHD0	Humeral cup - eccentric 0°
EAI CHC8	Humeral cup - centered 8°
EAI CH10	Humeral cup - high offset +10mm

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Concerned medical devices;

Product: ARAMIS-Total Shoulder Prosthesis

Reference	Designation
EAI IS06	Standard insert Ø38 / +6mm
EAI IS09	Standard insert Ø38 / +9mm
EAI IS12	Standard insert Ø38 / +12mm
EAI IR09	Retentive insert Ø38 / +9mm
EAI I406	Standard insert Ø42 / +6mm
EAI I409	Standard insert Ø42 / +9mm
EAI I412	Standard insert Ø42 / +12mm
EAI I4R9	Retentive insert Ø42 / +9mm
EAI SG38	Glenosphere Ø38mm
EAI SG42	Glenosphere Ø42mm
EAI SG35	Glenosphere Ø38mm for baseplate 25
EAI SC38	Cannulated glenosphere Ø38mm
EAI SC42	Cannulated glenosphere Ø42mm
EAI SC35	Cannulated glenosphere Ø38mm for baseplate 25
EAI OB28	Helicoidal baseplate - length 29mm
EAI OBHU	Universal helicoidal baseplate - length 26mm
EAI OBPS	Baseplate – standard peg
EAI OBRS	Baseplate reduced – standard peg
EAI OBPL	Baseplate – long peg
EAI OBRL	Baseplate reduced – long peg
EAI V515	Screw Ø5 length 15mm
EAI V520	Screw Ø5 length 20mm
EAI V525	Screw Ø5 length 25mm
EAI V530	Screw Ø5 length 30mm
EAI V535	Screw Ø5 length 35mm
EAI V540	Screw Ø5 length 40mm
EAI V545	Screw Ø5 length 45mm

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Certificate Number: 1984-MDD-20-704, Revision Number: 02

Concerned medical devices;

Product: IPP2 – Proximal Interphalangeal Prosthesis

Reference	Designation
IPP 001	Interphalangeal Hinge
IPP 3514	Interphalangeal screw Ø3.5 L14mm
IPP 4018	Interphalangeal screw Ø4 L18mm
IPP 5018	Interphalangeal screw Ø5 L18mm
IPP 6020	Interphalangeal screw Ø6 L20mm
IPP 7022	Interphalangeal screw Ø7 L22mm
IPP 8025	Interphalangeal screw Ø8 L25mm

Product: RUBIS MODULAR – Trapeziometacarpal Prosthesis

Reference	Designation
MRI CN00	Head- Size short
MRI CN05	Head- Size standard
MRI CN10	Head- Size long
MRI CI05	Cup - Size standard
MRI CI10	Cup - Size long
MRI TN00	Trapezial cup - Size 0
MRI TN01	Trapezial cup - Size 1
MRI TN02	Trapezial cup - Size 2
MRI TI00	Reversed trapezium - Size 0
MRI TI01	Reversed trapezium - Size 1
MRI TI02	Reversed trapezium - Size 2
MRI MM00	Metacarpal stem - Size 0
MRI MM05	Metacarpal stem - Size 5
MRI MM10	Metacarpal stem - Size 10
MRI MM20	Metacarpal stem - Size 20

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Full Quality Assurance System according to


Medical Devices Directive 93/42/EEC Annex-II.3

Certificate Number: 1984-MDD-20-704, Revision Number: 02

Concerned medical devices;

Product: Instruments ARAMIS range - Reusable surgical instrument with a connection to an active device

Reference	Designation
EAA FG25	Glenoid reamer Ø25mm
EAA FG30	Glenoid reamer Ø30mm
EAA FG33	Glenoid reamer Ø33mm
EAA FG36	Glenoid reamer Ø36mm
EAA MF00	Reamer handle
EAA M032	Drill Ø3.2mm L143mm
EAA MB80	Drill bit Ø8mm
EAA MP80	Cannulated drill for peg Ø8mm
EAA FC00	Surface planer- Ø30mm
EAA FC01	Surface planer – Ø40mm
EAA FC02	Surface planer- Ø45mm
EAA FC03	Surface planer – Ø50mm
ESA F001	Trephine – Size 1
ESA F002	Trephine – Size 2
ESA BG00	K-wire guide Ø2.5mm
ETA M032	Drill Ø3.2mm L240mm
ERA M040	Graduated drill Ø4mm
ERA MB50	Drill bit Ø5mm



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Certificate Number: 1984-MDD-20-704, Revision Number: 02

Concerned medical devices;

Product: ARAMIS-T – Trauma shoulder prosthesis

Reference	Designation
ETI T008	Trauma humeral stem Ø8.5mm
ETI T010	Trauma humeral stem Ø10mm
ETI T011	Trauma humeral stem Ø11.5mm
ETI V420	Locking screw Ø4mm L20mm
ETI V422	Locking screw Ø4mm L22mm
ETI V424	Locking screw Ø4mm L24mm
ETI V426	Locking screw Ø4mm L26mm
ETI V428	Locking screw Ø4mm L28mm
ETI V430	Locking screw Ø4mm L30mm
ETI V432	Locking screw Ø4mm L32mm
ETI V434	Locking screw Ø4mm L34mm
ETI V436	Locking screw Ø4mm L36mm
ETI V438	Locking screw Ø4mm L38mm
ETI V442	Locking screw Ø4mm L42mm
ETI V446	Locking screw Ø4mm L46mm
ETI V450	Locking screw Ø4mm L50mm
ETI PLUG	Obturator plug – conical and oblong

17 May 2021, Istanbul, Turkey

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Certificate Number: 1984-MDD-20-704, Revision Number: 02

Concerned medical devices;

Product: ARAMIS-T – Trauma humeral nail

Reference	Designation
ETI 1C07	Trauma humeral nail \varnothing 7mm - L135 mm
ETI 1C08	Trauma humeral nail \varnothing 8mm - L140mm
ETI 1C09	Trauma humeral nail \varnothing 9mm - L145mm
ETI 0C07	Trauma humeral nail \varnothing 7mm - L220mm
ETI 0C08	Trauma humeral nail \varnothing 8mm - L225mm
ETI 0C09	Trauma humeral nail \varnothing 9mm - L230mm

Product: ARAMIS-R – Revision shoulder prosthesis

Reference	Designation
ERI SH07	Humeral revision stem \varnothing 7/ L180mm – Total coating
ERI MH08	Locking humeral revision stem \varnothing 8.5/ L205mm - Total coating
ERI MH10	Locking humeral revision stem \varnothing 10/ L205mm - Total coating
ERI MH11	Locking humeral revision stem \varnothing 11.5/ L205mm - Total coating
ERI MH13	Locking humeral revision stem \varnothing 13/ L205mm - Total coating
ERI LH08	Locking humeral revision stem \varnothing 8.5/ L230mm - Total coating
ERI LH10	Locking humeral revision stem \varnothing 10/ L230mm - Total coating
ERI LH11	Locking humeral revision stem \varnothing 11.5/ L230mm - Total coating
ERI LH13	Locking humeral revision stem \varnothing 13/ L230mm - Total coating
ERI SP07	Humeral revision stem \varnothing 7/ L180mm - partial coating
ERI MP08	Locking humeral revision stem \varnothing 8.5/ L205mm - partial coating
ERI MP10	Locking humeral revision stem \varnothing 10/ L205mm - partial coating
ERI MP11	Locking humeral revision stem \varnothing 11.5/ L205mm - partial coating
ERI MP13	Locking humeral revision stem \varnothing 13/ L205mm - partial coating
ERI LP08	Locking humeral revision stem \varnothing 8.5/ L230mm - partial coating

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Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 4

Certificate Number: 1984-MDD-20-704, Revision Number: 02

Concerned medical devices;

Product: ARAMIS-R – Revision shoulder prosthesis

ERI LP10	Locking humeral revision stem \varnothing 10/ L230mm - partial coating
ERI LP11	Locking humeral revision stem \varnothing 11.5/ L230mm - partial coating
ERI LP13	Locking humeral revision stem \varnothing 13/ L230mm - partial coating
ERI C424	Locking pin \varnothing 4mm/L24mm
ERI C428	Locking pin \varnothing 4mm/L28mm
ERI C432	Locking pin \varnothing 4mm/L32mm
ERI C436	Locking pin \varnothing 4mm/L36mm
ERI C440	Locking pin \varnothing 4mm/L40mm
ERI K030	Keel glenoid \varnothing 30mm
ERI K033	Keel glenoid \varnothing 33mm
ERI K036	Keel glenoid \varnothing 36mm
ERI K136	Keel glenoid \varnothing 36mm R34
ERI OBLP	Baseplate – long peg with flat bottom

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

17 May 2021, Istanbul, Turkey

Muhteşem Gökhan Yücel
Head of Notified Body