



CERTIFICATE



This is to certify that the company

Feuerstein GmbH

Gustav-Krone-Straße 3
14167 Berlin
Germany

has implemented and maintains a **Quality Management System**.

Scope:

Development, manufacturing and distribution of surgical suture needles and drainage needles

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	092558 MP2016
Certificate unique ID	170778779
Effective date	2022-02-28
Expiry date	2025-02-27
Frankfurt am Main	2022-02-28



Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

EG-Konformitätserklärung *Declaration of Conformity*

Wir, die Firma

We, the company

Feuerstein GmbH, Gustav-Krone-Str. 3, D-14167 Berlin

erklären als Hersteller in alleiniger Verantwortung, dass das Medizinprodukt der Klasse I nach Anhang IX der Richtlinie 93/42/EWG

in our capacity as manufacturer declare in own responsibility that the medical device of class I according to Annex IX of Directive 93/42/EEC

Wundnadeln, unsteril – Artikel siehe Anhang

surgical needles, non-sterile – article see attachment

in Übereinstimmung mit der Richtlinie 93/42/EWG konstruiert und gefertigt ist und die Grundlegenden Anforderungen (Anhang I) erfüllt. Die Technische Dokumentation wird unter obiger Anschrift aufbewahrt. Die Konformitätsbewertung erfolgte in Übereinstimmung mit dem Anhang VII der Richtlinie 93/42/EWG. Anwendbare harmonisierte Normen wurden angewendet. Diese Erklärung ist gültig bis zum 25.05.2024.

is designed and manufactured in agreement with the guideline 93/42/EEC. The essential requirements according to Annex I are fulfilled. The technical documentation is kept under the address above. The conformity evaluation was performed according to annex VII of the guideline 93/42/EEC. Applicable harmonized standards were used. This declaration is valid until 25.05.2024.

Berlin, den 14.03.2022

Berlin, 14.03.2022

FEUERSTEIN GMBH
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Anhang EG-Konformitätserklärung
ANNEX of the declaration of conformity

Type	Code	Diameter x Length
GR	GR 514-000	1.80 x 100 mm
	GR 514-00	1.60 x 92 mm
	GR 514-0	1.60 x 85 mm
	GR 514-1	1.40 x 80 mm
	GR 514-2	1.40 x 75 mm
	GR 514-3	1.30 x 70 mm
	GR 514-4	1.30 x 65 mm
	GR 514-5	1.20 x 60 mm
	GR 514-6	1.20 x 55 mm
	GR 514-7	1.10 x 50 mm
	GR 514-8	1.00 x 45 mm
	GR 514-9	1.00 x 40 mm
	GR 514-10	0.90 x 36 mm
	GR 514-11	0.80 x 32 mm
	GR 514-12	0.80 x 28 mm
	GR 514-13	0.70 x 25 mm
GR 514-14	0.70 x 22 mm	
GR 514-15	0.60 x 20 mm	
GR 514-16	0.60 x 18 mm	
GAR	GAR 498-000	2.00 x 90 mm
	GAR 498-00	1.80 x 80 mm
	GAR 498-0	1.80 x 70 mm
	GAR 498-1	1.60 x 60 mm
	GAR 498-2	1.60 x 55 mm
	GAR 498-3	1.50 x 50 mm
	GAR 498-4	1.40 x 45 mm
	GAR 498-5	1.30 x 40 mm
	GAR 498-6	1.20 x 35 mm
	GAR 498-7	1.10 x 30 mm
	GAR 498-8	1.00 x 25 mm
	GAR 498-9	0.90 x 22 mm
	GAR 498-10	0.80 x 19 mm
GAR 498-11	0.80 x 16 mm	
Mayo	Mayo 542-1	1.50 x 50 mm
	Mayo 542-2	1.40 x 45 mm
	Mayo 542-3	1.40 x 42 mm
	Mayo 542-4	1.30 x 40 mm
Ferguson	Ferguson 546-1	1.40 x 74 mm
	Ferguson 546-2	1.30 x 63 mm
	Ferguson 546-3	1.10 x 50 mm
	Ferguson 546-4	1.00 x 40 mm
	Ferguson 546-5	0.80 x 34 mm
	Ferguson 546-6	0.70 x 23 mm

Type	Code	Diameter x Length
E	E 530-000	1.30 x 70 mm
	E 530-00	1.20 x 60 mm
	E 530-0	1.20 x 55 mm
	E 530-1	1.00 x 47 mm
	E 530-2	1.00 x 40 mm
	E 530-3	0.80 x 32 mm
	E 530-4	0.80 x 28 mm
	E 530-5	0.70 x 22 mm
GER	E 530-6	0.60 x 18 mm
	E 530-7	0.50 x 15 mm
	E 530-8	0.50 x 12 mm
	GER 566-1	1.40 x 80 mm
	GER 566-2	1.40 x 75 mm
	GER 566-3	1.30 x 70 mm
	GER 566-4	1.30 x 65 mm
	GER 566-5	1.20 x 60 mm
	GER 566-6	1.20 x 55 mm
	GER 566-7	1.10 x 52 mm
PB	GER 566-8	1.10 x 50 mm
	GER 566-9	1.00 x 47 mm
	GER 566-10	1.00 x 45 mm
	GER 566-11	1.00 x 40 mm
	GER 566-12	0.90 x 36 mm
	GER 566-13	0.90 x 30 mm
	GER 566-14	0.80 x 34 mm
	GER 566-15	0.80 x 32 mm
	GER 566-16	0.80 x 30 mm
	GER 566-17	0.80 x 28 mm
PB	GER 566-18	0.70 x 25 mm
	GER 566-19	0.70 x 23 mm
	GER 566-20	0.70 x 22 mm
	GER 566-21	0.60 x 20 mm
	GER 566-22	0.60 x 18 mm
	PB 538-00	0.80 x 75 mm
	PB 538-0	0.80 x 65 mm
	PB 538-1	0.70 x 55 mm
	PB 538-2	0.70 x 45 mm
	PB 538-3	0.60 x 36 mm
PB 538-4	0.60 x 30 mm	
PB 538-5	0.60 x 25 mm	
PB 538-6	0.60 x 22 mm	
PB 538-7	0.50 x 20 mm	
PB 538-8	0.50 x 18 mm	
PB 538-9	0.50 x 15 mm	
PB 538-10	0.50 x 12 mm	

Type	Code	Diameter x Length
BR	BR 510-000	1.80 x 100 mm
	BR 510-00	1.60 x 92 mm
	BR 510-0	1.60 x 85 mm
	BR 510-1	1.40 x 80 mm
	BR 510-2	1.40 x 75 mm
	BR 510-3	1.30 x 70 mm
	BR 510-4	1.30 x 65 mm
	BR 510-5	1.20 x 60 mm
	BR 510-6	1.20 x 55 mm
	BR 510-7	1.10 x 50 mm
	BR 510-8	1.00 x 45 mm
	BR 510-9	1.00 x 40 mm
	BR 510-10	0.90 x 36 mm
	BR 510-11	0.80 x 32 mm
	BR 510-12	0.80 x 28 mm
	BR 510-13	0.70 x 25 mm
BR 510-14	0.70 x 22 mm	
BR 510-15	0.60 x 20 mm	
BR 510-16	0.60 x 18 mm	
BER	BER 562-1	1.40 x 80 mm
	BER 562-2	1.40 x 75 mm
	BER 562-3	1.30 x 70 mm
	BER 562-4	1.30 x 65 mm
	BER 562-5	1.20 x 60 mm
	BER 562-6	1.20 x 55 mm
	BER 562-7	1.10 x 52 mm
	BER 562-8	1.10 x 50 mm
	BER 562-9	1.00 x 47 mm
	BER 562-10	1.00 x 45 mm
	BER 562-11	1.00 x 40 mm
	BER 562-12	0.90 x 36 mm
	BER 562-13	0.90 x 30 mm
	BER 562-14	0.80 x 34 mm
	BER 562-15	0.80 x 32 mm
	BER 562-16	0.80 x 30 mm
BER 562-17	0.80 x 28 mm	
BER 562-18	0.70 x 25 mm	
BER 562-19	0.70 x 23 mm	
BER 562-20	0.70 x 22 mm	
BER 562-21	0.60 x 20 mm	
BER 562-22	0.60 x 18 mm	

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Type	Code	Diameter x Length
PD	PD 534-00	0.80 x 75 mm
	PD 534-0	0.80 x 65 mm
	PD 534-1	0.70 x 55 mm
	PD 534-2	0.70 x 45 mm
	PD 534-3	0.60 x 36 mm
	PD 534-4	0.60 x 30 mm
	PD 534-5	0.60 x 25 mm
	PD 534-6	0.60 x 22 mm
	PD 534-7	0.50 x 20 mm
	PD 534-8	0.50 x 18 mm
HR	HR 422-00	1.40 x 75 mm
	HR 422-0	1.20 x 60 mm
	HR 422-1	1.10 x 52 mm
	HR 422-2	1.00 x 45 mm
	HR 422-3	0.90 x 38 mm
	HR 422-4	0.80 x 30 mm
	HR 422-5	0.70 x 22 mm
PH	PH 544-00	0.80 x 75 mm
	PH 544-0	0.80 x 65 mm
	PH 544-1	0.70 x 55 mm
	PH 544-2	0.70 x 45 mm
	PH 544-3	0.60 x 36 mm
	PH 544-4	0.60 x 30 mm
	PH 544-5	0.60 x 25 mm
	PH 544-6	0.60 x 22 mm
	PH 544-7	0.50 x 20 mm
	PH 544-8	0.50 x 18 mm
OG	OG 554-0	0.60 x 36 mm
	OG 554-1	0.60 x 30 mm
	OG 554-2	0.50 x 25 mm
	OG 554-3	0.50 x 21 mm
	OG 554-4	0.50 x 18 mm
	OG 554-5	0.50 x 15 mm
Hernia	Hernia 572-1	1.40 x 45 mm
	Hernia 572-2	1.30 x 40 mm
	Hernia 572-3	1.20 x 35 mm
	Hernia 572-4	1.10 x 30 mm

Type	Code	Diameter x Length
G	G 504-000	1.80 x 100 mm
	G 504-00	1.60 x 92 mm
	G 504-0	1.60 x 85 mm
	G 504-1	1.40 x 80 mm
	G 504-2	1.40 x 75 mm
	G 504-3	1.30 x 70 mm
	G 504-4	1.30 x 65 mm
	G 504-5	1.20 x 60 mm
	G 504-6	1.20 x 55 mm
	G 504-7	1.10 x 50 mm
	G 504-8	1.00 x 45 mm
	G 504-9	1.00 x 40 mm
	G 504-10	0.90 x 36 mm
	G 504-11	0.80 x 32 mm
	G 504-12	0.80 x 28 mm
	G 504-13	0.70 x 25 mm
GA	GA 508-000	2.00 x 90 mm
	GA 508-00	1.80 x 80 mm
	GA 508-0	1.80 x 70 mm
	GA 508-1	1.60 x 60 mm
	GA 508-2	1.60 x 55 mm
	GA 508-3	1.50 x 50 mm
	GA 508-4	1.40 x 45 mm
	GA 508-5	1.30 x 40 mm
	GA 508-6	1.20 x 35 mm
	GA 508-7	1.10 x 30 mm
	GA 508-8	1.00 x 25 mm
GA 508-9	0.90 x 22 mm	
GA 508-10	0.80 x 19 mm	
GA 508-11	0.80 x 16 mm	

Type	Code	Diameter x Length
GE	GE 548-1	1.40 x 80 mm
	GE 548-2	1.40 x 75 mm
	GE 548-3	1.30 x 70 mm
	GE 548-4	1.30 x 65 mm
	GE 548-5	1.20 x 60 mm
	GE 548-6	1.20 x 55 mm
	GE 548-7	1.10 x 52 mm
	GE 548-8	1.10 x 50 mm
	GE 548-9	1.00 x 47 mm
	GE 548-10	1.00 x 45 mm
	GE 548-11	1.00 x 40 mm
	GE 548-12	0.90 x 36 mm
	GE 548-13	0.90 x 30 mm
	GE 548-14	0.80 x 34 mm
	GE 548-15	0.80 x 32 mm
	GE 548-16	0.80 x 30 mm
	GE 548-17	0.80 x 28 mm
	GE 548-18	0.70 x 25 mm
	GE 548-19	0.70 x 23 mm
	GE 548-20	0.70 x 22 mm
	GE 548-21	0.60 x 20 mm
	GE 548-22	0.60 x 18 mm
B	B 502-000	1.80 x 100 mm
	B 502-00	1.60 x 92 mm
	B 502-0	1.60 x 85 mm
	B 502-1	1.40 x 80 mm
	B 502-2	1.40 x 75 mm
	B 502-3	1.30 x 70 mm
	B 502-4	1.30 x 65 mm
	B 502-5	1.20 x 60 mm
	B 502-6	1.20 x 55 mm
	B 502-7	1.10 x 50 mm
	B 502-8	1.00 x 45 mm
	B 502-9	1.00 x 40 mm
	B 502-10	0.90 x 36 mm
	B 502-11	0.80 x 32 mm
	B 502-12	0.80 x 28 mm
	B 502-13	0.70 x 25 mm
B 502-14	0.70 x 22 mm	
B 502-15	0.60 x 20 mm	
B 502-16	0.60 x 18 mm	

Type	Code	Diameter x Length
BE	BE 560-1	1.40 x 80 mm
	BE 560-2	1.40 x 75 mm
	BE 560-3	1.30 x 70 mm
	BE 560-4	1.30 x 65 mm
	BE 560-5	1.20 x 60 mm
	BE 560-6	1.20 x 55 mm
	BE 560-7	1.10 x 52 mm
	BE 560-8	1.10 x 50 mm
	BE 560-9	1.00 x 47 mm
	BE 560-10	1.00 x 45 mm
	BE 560-11	1.00 x 40 mm
	BE 560-12	0.90 x 36 mm
	BE 560-13	0.90 x 30 mm
	BE 560-14	0.80 x 34 mm
	BE 560-15	0.80 x 32 mm
	BE 560-16	0.80 x 30 mm
	BE 560-17	0.80 x 28 mm
	BE 560-18	0.70 x 25 mm
	BE 560-19	0.70 x 23 mm
	BE 560-20	0.70 x 22 mm
	BE 560-21	0.60 x 20 mm
	BE 560-22	0.60 x 18 mm
OB	OB 552-0	0.60 x 36 mm
	OB 552-1	0.60 x 30 mm
	OB 552-2	0.50 x 25 mm
	OB 552-3	0.50 x 21 mm
	OB 552-4	0.50 x 18 mm
	OB 552-5	0.50 x 15 mm
OB 552-6	0.50 x 12 mm	

Type	Code	Diameter x Length
H	H 522-00	1.40 x 75 mm
	H 522-0	1.20 x 60 mm
	H 522-1	1.10 x 52 mm
	H 522-2	1.00 x 45 mm
	H 522-3	0.90 x 38 mm
	H 522-4	0.80 x 30 mm
	GT	GT 516-000
GT 516-00		1.60 x 92 mm
GT 516-0		1.60 x 85 mm
GT 516-1		1.40 x 80 mm
GT 516-2		1.40 x 75 mm
GT 516-3		1.30 x 70 mm
GT 516-4		1.30 x 65 mm
GT 516-5		1.20 x 60 mm
GT 516-6		1.20 x 55 mm
GT 516-7		1.10 x 50 mm
GT 516-8		1.00 x 45 mm
GT 516-9		1.00 x 40 mm
GT 516-10		0.90 x 36 mm
GT 516-11		0.80 x 32 mm
GT 516-12		0.80 x 28 mm
GT 516-13		0.70 x 25 mm
GT 516-14	0.70 x 22 mm	
GT 516-15	0.60 x 20 mm	
GT 516-16	0.60 x 18 mm	
GAT	GAT 500-000	2.00 x 90 mm
	GAT 500-00	1.80 x 80 mm
	GAT 500-0	1.80 x 70 mm
	GAT 500-1	1.60 x 60 mm
	GAT 500-2	1.60 x 55 mm
	GAT 500-3	1.50 x 50 mm
	GAT 500-4	1.40 x 45 mm
	GAT 500-5	1.30 x 40 mm
	GAT 500-6	1.20 x 35 mm
	GAT 500-7	1.10 x 30 mm
	GAT 500-8	1.00 x 25 mm
GAT 500-9	0.90 x 22 mm	
GAT 500-10	0.80 x 19 mm	
GAT 500-11	0.80 x 16 mm	

Type	Code	Diameter x Length
ET	ET 528-000	1.30 x 70 mm
	ET 528-00	1.20 x 60 mm
	ET 528-0	1.20 x 55 mm
	ET 528-1	1.00 x 47 mm
	ET 528-2	1.00 x 40 mm
	ET 528-3	0.80 x 32 mm
	ET 528-4	0.80 x 28 mm
	ET 528-5	0.70 x 22 mm
	ET 528-6	0.60 x 18 mm
	ET 528-7	0.50 x 15 mm
	ET 528-8	0.50 x 12 mm
Mayo	Mayo T 442-1	1.50 x 50 mm
	Mayo T 442-2	1.40 x 45 mm
	Mayo T 442-3	1.40 x 42 mm
	Mayo T 442-4	1.30 x 40 mm
Keith	Keith 518-0	1.00 x 80 mm
	Keith 518-1	0.90 x 75 mm
	Keith 518-2	0.90 x 70 mm
	Keith 518-3	0.90 x 65 mm
	Keith 518-4	0.80 x 60 mm
	Keith 518-5	0.80 x 55 mm
	Keith 518-6	0.80 x 50 mm
	Keith 518-7	0.70 x 45 mm
	Keith 517-0	1.00 x 80 mm
	Keith 517-1	0.90 x 75 mm
	Keith 517-2	0.90 x 70 mm
	Keith 517-3	0.90 x 65 mm
	Keith 517-4	0.80 x 60 mm
	Keith 517-5	0.80 x 55 mm
Keith 517-6	0.80 x 50 mm	
Keith 517-7	0.70 x 45 mm	

Type	Code	Diameter x Length
OA	OA 550-0	0.60 x 36 mm
	OA 550-1	0.60 x 30 mm
	OA 550-2	0.50 x 25 mm
	OA 550-3	0.50 x 21 mm
	OA 550-4	0.50 x 18 mm
	OA 550-5	0.50 x 15 mm
	OA 550-6	0.50 x 12 mm
	OA 549-0	0.60 x 36 mm
	OA 549-1	0.60 x 30 mm
	OA 549-2	0.50 x 25 mm
	OA 549-3	0.50 x 21 mm
	OA 549-4	0.50 x 18 mm
	OA 549-5	0.50 x 15 mm
	OA 549-6	0.50 x 12 mm
PM	PM/A 623-1	2.00 x 145 mm
	PM/A 623-2	2.00 x 30 mm
	PM/A 623-3	2.00 x 115 mm
	PM/A 623-4	2.00 x 100 mm
	PM/A 623-5	1.80 x 85 mm
	PM/A 623-6	1.80 x 75 mm
AV	AV 590-1	2.00 x 100 mm
	AV 590-2	2.00 x 90 mm
	AV 590-3	1.80 x 80 mm
	AV 590-4	1.80 x 70 mm
	AV 590-5	1.60 x 60 mm
	AV 590-6	1.60 x 55 mm
	AV 590-7	1.50 x 50 mm
	AV 590-8	1.40 x 45 mm
	AV 590-9	1.30 x 40 mm
	AV 590-10	1.20 x 35 mm
	AV 590-11	1.10 x 30 mm
	AV 590-12	1.00 x 25 mm
	AV 590-13	0.90 x 22 mm

Type	Code	Diameter x Length
A	A 506-000	1.80 x 100 mm
	A 506-00	1.60 x 92 mm
	A 506-0	1.60 x 85 mm
	A 506-1	1.40 x 80 mm
	A 506-2	1.40 x 75 mm
	A 506-3	1.30 x 70 mm
	A 506-4	1.30 x 65 mm
	A 506-5	1.20 x 60 mm
	A 506-6	1.20 x 55 mm
	A 506-7	1.10 x 50 mm
	A 506-8	1.00 x 45 mm
	A 506-9	1.00 x 40 mm
	A 506-10	0.90 x 36 mm
	A 506-11	0.80 x 32 mm
	A 506-12	0.80 x 28 mm
	A 506-13	0.70 x 25 mm
	A 506-14	0.70 x 22 mm
	A 506-15	0.60 x 20 mm
	A 506-16	0.60 x 18 mm
	A 505-000	1.80 x 100 mm
	A 505-00	1.60 x 92 mm
	A 505-0	1.60 x 85 mm
	A 505-1	1.40 x 80 mm
	A 505-2	1.40 x 75 mm
	A 505-3	1.30 x 70 mm
	A 505-4	1.30 x 65 mm
	A 505-5	1.20 x 60 mm
	A 505-6	1.20 x 55 mm
	A 505-7	1.10 x 50 mm
	A 505-8	1.00 x 45 mm
	A 505-9	1.00 x 40 mm
	A 505-10	0.90 x 36 mm
A 505-11	0.80 x 32 mm	
A 505-12	0.80 x 28 mm	
A 505-13	0.70 x 25 mm	
A 505-14	0.70 x 22 mm	
A 505-15	0.60 x 20 mm	
A 505-16	0.60 x 18 mm	

EG-Konformitätserklärung *Declaration of Conformity*

Wir, die Firma

We, the company

Feuerstein GmbH, Gustav-Krone-Str. 3, D-14167 Berlin

erklären als Hersteller in alleiniger Verantwortung, dass das Medizinprodukt der Klasse I nach Anhang IX der Richtlinie 93/42/EWG

in our capacity as manufacturer declare in own responsibility that the medical device of class I according to Annex IX of Directive 93/42/EEC

Wundnadeln, unsteril – Artikel siehe Anhang

surgical needles, non-sterile – article see attachment

in Übereinstimmung mit der Richtlinie 93/42/EWG konstruiert und gefertigt ist und die Grundlegenden Anforderungen (Anhang I) erfüllt. Die Technische Dokumentation wird unter obiger Anschrift aufbewahrt. Die Konformitätsbewertung erfolgte in Übereinstimmung mit dem Anhang VII der Richtlinie 93/42/EWG. Anwendbare harmonisierte Normen wurden angewendet. Diese Erklärung ist gültig bis zum 25.05.2024.

is designed and manufactured in agreement with the guideline 93/42/EEC. The essential requirements according to Annex I are fulfilled. The technical documentation is kept under the address above. The conformity evaluation was performed according to annex VII of the guideline 93/42/EEC. Applicable harmonized standards were used. This declaration is valid until 25.05.2024.

Berlin, den 04.09.2023

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Anhang EG-Konformitätserklärung
ANNEX of the declaration of conformity

Type	Code	Diameter x Length
BT	BT 512-000	1.80 x 100 mm
	BT 512-00	1.60 x 92 mm
	BT 512-0	1.60 x 85mm
	BT 512-1	1.40 x 80 mm
	BT 512-2	1.40 x 75 mm
	BT 512-3	1.30 x 70 mm
	BT 512-4	1.30 x 65 mm
	BT 512-5	1.20 x 60 mm
	BT 512-6	1.20 x 55 mm
	BT 512-7	1.10 x 50 mm
	BT 512-8	1.00 x 45 mm
	BT 512-9	1.00 x 40 mm
	BT 512-10	0.90 x 36 mm
	BT 512-11	0.80 x 32 mm
	BT 512-12	0.80 x 28 mm
	BT 512-13	0.70 x 25 mm
BT 512-14	0.70 x 22 mm	
BT 512-15	0.60 x 20 mm	
BT 512-16	0.60 x 18 mm	

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