SZUTEST

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-391435901

Manufacturer:	**NEO Dr. INC.** #2-204, 205, Medical Industry Complex, 42-10, Taejanggongdan-gil, Wonju-si, Gangwon-do, Republic of KOREA
Product(s):	**Sterile Single Use Absorbable Polydioxanone Suture with Needle**
Model(s):	**Normal Type** Mono Type, Screw Type, Double Screw Type, Cavern Screw Type, Jamber Type, Jamber Reverse Type, Jamber Tanxing Type, Jamber Tanxing Two Pitch Type, Jamber F Type, Jamber I Type, Double Type, Triple Type, Multi Thread Type **Cog Type** SPR(S2N1R1) Type, 4D Type, SPR(S4N3R1) Type, ORG Type, NEO Type, BDST Type, BDS Type, MDT Type, MD Type, SPR(S3N1R1) Type, SPR(S4N1R1) Type, SPR(S2N3R1) Type, SPR(S3N3R1) Type, SPK Type, CleoKo Type, CleoKo 2 Type, Cog Screw Type, Cog Screw 2 Type, Anchoring Cog Type, Jamber Anchoring Cog Type, SPR(S6N1R1) Type, SPR(S6N3R1) Type
Reference Report No:	MM0390-P007-R01, MM0390-P007-R02, MM0390-P008-R01, MM0390-P008-R02, MM0390-P012-R01, MM0390-P012-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

This EC certificate is valid till 2024-01-08.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Issue Date:	2014-12-25
Revision No.:	05 Rev.
Revision Date:	2021-03-15

Rukiye BALKAN
Deputy General Manager

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number: 2195-MED-391435901-D01

Manufacturer:	**NEO Dr. INC.** #2-204, 205, Medical Industry Complex, 42-10, Taejanggongdan-gil, Wonju-si, Gangwon-do, Republic of KOREA
Product(s):	**Sterile Single Use Absorbable Polydioxanone Suture with Needle**
Model(s):	**Normal Type** Mono Type, Screw Type, Double Screw Type, Cavern Screw Type, Jamber Type, Jamber Reverse Type, Jamber Tanxing Type, Jamber Tanxing Two Pitch Type, Jamber F Type, Jamber I Type, Double Type, Triple Type, Multi Thread Type
Reference Report No:	MM0390-P007-R01, MM0390-P007-R02, MM0390-P008-R01, MM0390-P008-R02, MM0390-P012-R01, MM0390-P012-R02

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

This EC Design Examination certificate is valid till 2024-01-08.

Issue Date:	2014-12-25
Revision No.:	05 Rev.
Revision Date:	2021-03-15

Rukiye BALKAN
Deputy General Manager

This version of certificate has come into force on 23.03.2017. 1/1. 2195-MED-391435901-D01 Rev.05

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number: 2195-MED-391435901-D02

Manufacturer:	**NEO Dr. INC.** #2-204, 205, Medical Industry Complex, 42-10, Taejanggongdan-gil, Wonju-si, Gangwon-do, Republic of KOREA, 26311
Product(s):	**Sterile Single Use Absorbable Polydioxanone Suture with Needle**
Model(s):	**Cog Type** SPR(S2N1R1) Type, 4D Type, SPR(S4N3R1) Type, ORG Type, NEO Type, BDST Type, BDS Type, MDT Type, MD Type, SPR(S3N1R1) Type, SPR(S4N1R1) Type, SPR(S2N3R1) Type, SPR(S3N3R1) Type, SPK Type, CleoKo Type, CleoKo 2 Type, Cog Screw Type, Cog Screw 2 Type, Anchoring Cog Type, Jamber Anchoring Cog Type, SPR(S6N1R1) Type, SPR(S6N3R1) Type
Reference Report No:	MM0390-P007-R01, MM0390-P007-R02, MM0390-P012-R01, MM0390-P012-R02

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

This EC Design Examination certificate is valid till 2024-01-08.

Issue Date:	2014-12-25
Revision No.:	04 Rev.
Revision Date:	2021-03-15

Rukiye BALKAN
Deputy General Manager

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Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr