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according to the Medical Devices Directive 93/42/EEC amended by 2007/47/EC

Manufacturer:	<i>NEO Dr. INC.</i>
Address	<i>#2-204, 205, Medical Industry Complex, 42-10 Taejunggongdan-gil, Wonju-si, Gangwon-do, Republic of Korea 26311</i>
European Representative:	KTR Europe GmbH
Address	Mergenthalerallee 77, Eschborn, Hessen, 65760, Germany
Product :	<i>STERILE SINGLE USE ABSORBABLE POLYDIOXANONE SUTURE WITH NEEDLE</i>
Brand Name:	<i>Dr. perfect V-line, NEO LINE, Henry.C, FOX2660, FOX2638, Magic Face, Bidan Energy, Nubelline[®], Dr. CAVERN[®], NOVACUTAN[®]; VIFINY[®]; BEAULIGNE[®], RHANCHOR[®], TANXING CAVERN, JAMBER[®], Reborn, DERIC, epiticon JAMBER, ReMedium Line</i>
Type name(s):	<i>See Attachment.</i>
Classification :	<i>Class III by Rule 8 of Annex IX, Council Directive 93/42/EEC</i>
GMDN Code:	<i>16584</i>

The product identified above complies with the essential requirements of the above EC Directives by meeting the following standards:

EN ISO 13485:2016	ISO 10993-10:2013	ISO 14698-2:2003
EN ISO 14971:2012	EN ISO 10993-11: 2009	EN ISO 11135-1:2007
ISO/TR 24971:2013	EN ISO 10993-13:2010	EN ISO 11138-2:2017
MEDDEV 2.7.1 Rev 4	ISO/TR 10993-33:2015	EN ISO 11737-1:2006
MEDDEV 2.12/2 Rev 2	ISO 14644-1:2015	EN ISO 11737-2:2009
MEDDEV 2.12/1 Rev 8	ISO 14644-2:2015	EN 556-1:2001/AC:2006
EN 1041:2008	ISO 14644-3:2005	EN ISO 11607-1: 2009
ISO 15223-1:2016	ISO 14644-4:2001	EN ISO 11607-2: 2006
EN 62366:2008	ISO 14644-5:2004	ISO 9626:2016
EN ISO 10993-1:2009	ISO 14644-6:2007	ISO 7864:2016
EN ISO 10993-3:2014	ISO 14644-7:2004	ISO 6009:2016
EN ISO 10993-4:2009	ISO 14644-8:2013	EN 20594-1:1994
EN ISO 10993-5:2009	ISO 14644-9:2012	EP 01/2008:0666
EN ISO 10993-6:2009	ISO 14644-10:2013	USP 921
EN ISO 10993-7:2008	ISO 14698-1:2003	ISO 17025:2017
EN ISO 10993-9:2009		

This Declaration of Conformity is based on the EC Directives 93/42/EEC as amended by 2007/47/EC, Annex II (including section 4) under the supervision of Notified body, Szutest Uygunluk Degerlendirme Anonim Sirketi (2195).



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Notified body:

Szutest Uygunluk Degerlendirme Anonim Sirketi
Tatlısu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul

EC Certificate No.: 2195-MED-391435901

Issue date: Dec.25,2014

Expiration date: Jan.08,2024

Place: Wonju-si, Gangwon-do, Korea

Date: September 09. 2021

Hyeon Ho, Kim

Representative of NEO Dr. INC.

- Attached : Annex17_Model Description