CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

M.2019.106.11953-1 Design Examination Certificate Was Prepared for Class III Products Defined in This Certificate.

Company Name	: Huaian Pingan Medical Instrument Co., Ltd.
Company Address	: No:128 West Meigao Road, Huaian, Jiangsu, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Sterile, Absorbable Polyglactin 910 (PGLA) suture with or without needle - Class III - Sterile, Absorbable Polyglycolic Acid (PGA) suture with or without needle - Class III - Sterile, Absorbable Polydioxanone (PDO) suture with or without needle - Class III - Sterile, Absorbable Poliglecaprone (PGCL) suture with or without needle - Class III
GMDN	: 17471, 13908, 16584, 17246
	Product Types are attached.
Certificate Number	: M.2019.106.11953
Report Number	: MD.3625.IB
Initial Assessment Date	: 09.04.2018
Registration Date	: 14.05.2019
Revision Date /No	: -
Expiry Date	: 13.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara / TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

Digitally signed by Iarovoi Petru
Date: 2021.12.16 14:03:04 EET
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE

EC Design-Examination Certificate

93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2019.106.11953 the validity of the certificate M.2019.106.11953-1 will also end.

Company Name	: Huaian Pingan Medical Instrument Co., Ltd.
Company Address	: No:128 West Meigao Road, Huaian, Jiangsu, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Section 4)
Product	: - Sterile, Absorbable Polyglactin 910 (PGLA) suture with or without needle - Class III - Sterile, Absorbable Polyglycolic Acid (PGA) suture with or without needle - Class III - Sterile, Absorbable Polydioxanone (PDO) suture with or without needle - Class III - Sterile, Absorbable Poliglecaprone (PGCL) suture with or without needle - Class III
GMDN	: 17471, 13908, 16584, 17246

Product Types are attached.

Certificate Number	: M.2019.106.11953-1
Report Number	: MD.3625.IB
Initial Assessment Date	: 09.04.2018
Registration Date	: 14.05.2019
Revision Date /No	: -
Expiry Date	: 13.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc., Co.

The EC desing examination certificate refers to the above mentioned product. UDEM hereby declares that the requirements of Annex II, section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the aforementioned directive. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Huaian Pingan Medical InstrumentCo., Ltd.
Company Address	: No:128 West Meigao Road, Huaian, Jiangsu, China
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: - Sterile, Non-Absorbable Silk Braided Suture with or without needle - Class IIb - Sterile, Non-Absorbable Polyester Braided Suture with or without needle - Class IIb - Sterile, Non-Absorbable Polypropylene monofilament Suture with or without needle - Class IIb - Sterile, Non-Absorbable Nylon / Polyamide monofilament Suture with or without needle - Class IIb
GMDN	: 13910, 13906, 13909, 13905

Product Types are attached.

Certificate Number	: M.2019.106.11952
Report Number	: MD.3625.IB
Initial Assessment Date	: 09.04.2018
Registration Date	: 14.05.2019
Revision Date /No	: -
Expiry Date	: 13.05.2024

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. UDEM's responsibility for class I devices covered by the EC sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returnedupon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com. tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr

UDEM Adriatic d.o.o.
Radnička cesta 54/R3
10000 Zagreb, CROATIA

2024/06/04

HUAIAN PINGAN MEDICAL INSTRUMENT CO.,LTD
No:128 West Meigao Road ,
Huaian,Jiangsu,
China

NOTIFIED BODY CONFIRMATION LETTER

Reference: 2023.MDR.1717.NBCL.0050/R01

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, UDEM ADRIATIC D.O.O., a Notified Body (NB) designated under Regulation (EU) 2017/745 (MDR) and identified by the number 2696 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR (on the date of 2023/07/18) and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR (on the date of 2023/07/18) with the following manufacturer:

HUAIAN PINGAN MEDICAL INSTRUMENT CO.,LTD
No:128 West Meigao Road ,
Huaian,Jiangsu,
China
SRN Number (if available): CN-MF-000010430

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD). Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but UDEM Adriatic d.o.o. has not yet taken the responsibility for appropriate surveillance of the corresponding devices under MDD.

UDEM Adriatic d.o.o.
UDEM OIB:503730[illegible]9784
Radnička cesta 54/R3, Green Gold Centar, [illegible]kat Zagreb
Tel:(1)4819601 Fax:(1)4819434
www.udemadriatic.com

In the case of devices covered by certificates issued under MDD that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 March 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of UDEM Adriatic d.o.o.

Zekeriya AYTAÇ

General Manager

UDEM Adriatic d.o.o.
UDEM OIB:50373079784
Radnička cesta 54/R3, Green Gold Centar,IV.kat.Zagreb
Tel:(1)4819601 Fax: (1)4819434
www.udemadriatic.com

UDEM Adriatic d.o.o.
UDEM OIB:50373079784
Radnička cesta 54/R3, Green Gold Centar,IV.kat.Zagreb
Tel:(1)4819601 Fax: (1)4819434
www.udemadriatic.com

Table 1: Devices covered by this letter and for which UDEM Adriatic d.o.o. is also responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile,Absorbable Polyglactin 910(PGLA) Suture with or without needle	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2019.106.11953 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 2:** EC Design-Examination Certificate No: M. 2019.106.11953-1 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
Sterile,Absorbable Polyglycolic Acid(PGA) Suture with or without needle	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2019.106.11953 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292) **Certificate 2:** EC Design-Examination Certificate No: M. 2019.106.11953-1 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
Sterile,Absorbable Polydioxanone(PDO) Suture with or without needle	Class III	N/A	**Certificate 1:** Full Quality Assurance System Certificate No: M.2019.106.11953

UDEM Adriatic d.o.o.
UDEM OIB:503730[illegible]
Radnička cesta 54/R3, Green Gold Centar,IV.kat,Zagreb
Tel:(1)4819601 Fax: (1)4819434
www.udemadriatic.com

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292) **<u>Certificate 2:</u>** EC Design-Examination Certificate No: M. 2019.106.11953-1 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
Sterile,Non-Absorbable Silk Braided Suture with or without needle	Class IIb excluding Class IIb implantable non-WET	N/A	**<u>Certificate 1:</u>** Full Quality Assurance System Certificate No: M.2019.106.11952 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
Sterile,Non-Absorbable Polypropylene Monofilament Suture with or without needle	Class IIb excluding Class IIb implantable non-WET	N/A	**<u>Certificate 1:</u>** Full Quality Assurance System Certificate No: M.2019.106.11952 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)
Sterile,Non-Absorbable Nylon/Polyamide monofilament Suture with or without needle	Class IIb excluding Class IIb implantable non-WET	N/A	**<u>Certificate 1:</u>** Full Quality Assurance System Certificate No: M.2019.106.11952 UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. (NB2292)

UDEM Adriatic d.o.o.
UDEM OIB:50373079781
Radnička cesta 54/R3, Green Gold Centar,IV.kat.Zagreb
Tel:(1)4819601 Fax:(1)4819434
www.udemadriatic.com

Table 2: Devices covered by this letter and for which UDEM Adriatic d.o.o. is NOT responsible for appropriate surveillance of the corresponding devices under Directive 93/42/EEC (MDD)

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/12/25	2023.MDR.1717.NBCL.0050	Initial issue
2024/06/04	2023.MDR.1717.NBCL.0050/R01	On the date of 2024/04/17, MDD survaillance of related legacy devices was transferred to UDEM Adriatic d.o.o from MDD Notified Body (NB2292).For this reason, the related devices have been moved from Table 2 to Table 1 of this letter.

UDEM Adriatic d.o.o.
UDEM OIB:50373079784
Radnička cesta 54/R3, Green Gold Centar IV.kat Zagreb
Tel:(1)4819601 Fax:(1)4819434
www.udemadriatic.com

Medical Devices Quality Management System

QAS INTERNATIONAL

Certificate

This is to certify that the Medical Devices Quality Management System of

HUAIAN PINGAN MEDICAL INSTRUMENT CO., LTD.

Located at.

No:128, West Meigao Road, Huaian, Jiangsu , China.

has been found to comply with

ISO 13485: 2016

For the following scope:

DESIGN & DEVELOPMENT, PRODUCTION AND SALES OF ABSORBABLE AND NON-ABSORBABLE SUTURES WITH OR WITHOUT NEEDLE, SUTURE NEEDLES.

GROUP CODE

A-D

Certificate Issuance: 22.07.2025
Certificate Expiry: 22.07.2028

1st Surveillance: 22.07.2026
2nd Surveillance: 22.07.2027

Certificate No: QAMD20241029

Authorized Signatory

QAS INTERNATIONAL:CAB No.012206B

EGAC Accredited
CAB No.012206B

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

QAS INTERNATIONAL, is Accredited Body by EGAC, under IAF Recognized, Box 1811 Chelsea Quebec J9B 1A1 Canada the validity of this certificate can be verified at www.qasinternational.org or through info@qasinternational.org. This certificate is the property of QAS international and must be returned on requested.