CERTIFICATO CE

Certificato n. 1694/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Visto l'esito delle verifiche condotte in conformità all'Allegato II, con l'esclusione del punto 4, della direttiva 93/42/CEE e s.m.i., si dichiara che la ditta:

TRIDENT SRL

20124 MILANO (MI) - VIALE VITTORIO VENETO 6 (ITA) - Italy

mantiene nello stabilimento di:

25014 CASTENEDOLO (BS) - VIA ARTIGIANI 4 (ITA) - Italy

un sistema qualità che assicura la conformità dei seguenti prodotti:

Sistemi radiografici endorali
Mod. RiX70 DC.
Marca Trident

Sistemi digitali per l'acquisizione ed elaborazione di immagini radiologiche dentali
Modd. I-View; I-View size 2.
Marca Trident

Apparecchio per la rilevazione di immagini radiologiche intraorali
Mod. READER.
Marca Trident

Sistemi radiologici panoramici e cefalometrici
Modd. X-VIEW 3D PAN; X-VIEW 2D PAN.
Marca Trident

ai requisiti essenziali della direttiva suddetta ad essi applicabili (in tutte le fasi dalla progettazione al controllo finale) ed è sottoposta alla sorveglianza prevista dal punto 5 dell'Allegato II. Per i dispositivi in classe III questo certificato è valido solamente con il relativo certificato di esame CE della progettazione di Allegato II.4.

Riferimento pratiche IMQ:
10AN00101; DM15A0468762-01; DM15A0544164-01; DM16E0653471-01; DM16-0004740-01; DM17-0015932-01; DM19-0037138-01.

Digitally signed by Savca Octavian
Date: 2019.10.25 12:28:44 EEST
Reason: MoldSign Signature
Location: Moldova

Emesso il:	2014-08-01
Data aggiornamento:	2019-07-29
Sostituisce:	2018-01-15
Data scadenza:	2024-05-26

IMQ

CERTIFICATO CE

Certificato n. 1694/MDD

Dichiarazione di approvazione del sistema qualità

(Sistema completo di garanzia qualità)

Questa Dichiarazione di approvazione è rilasciata dall'IMQ S.p.A. quale organismo notificato per la direttiva 93/42/CEE e s.m.i. Il numero identificativo dell'IMQ S.p.A. quale organismo notificato è: 0051.

Emesso il:	2014-08-01
Data aggiornamento:	2019-07-29
Sostituisce:	2018-01-15
Data scadenza:	2024-05-26

IMQ

EC CERTIFICATE

Certificate No 1694/MDD

Full Quality Assurance System Approval Certificate

On the basis of our examination carried out according to Annex II, excluding section 4, of the Directive 93/42/EEC and its revised version, we hereby certify that:

TRIDENT SRL

20124 MILANO (MI) - VIALE VITTORIO VENETO 6 (ITA) - Italy

manages in the factory of:

25014 CASTENEDOLO (BS) - VIA ARTIGIANI 4 (ITA) - Italy

a quality assurance system ensuring the conformity of the following products:

Dental intraoral systems
Type ref. RiX70 DC.
Trade mark Trident

Digital system for acquisition and processing of dental x-ray images
Type ref. I-View; I-View size 2.
Trade mark Trident

Devices for recording X-ray imaging for intra oral dental images
Type ref. READER.
Trade mark Trident

Panoramic and cephalometric X-ray systems
Type ref. X-VIEW 3D PAN; X-VIEW 2D PAN.
Trade mark Trident

with the relevant essential requirements of the aforementioned directive (from design to final inspection and testing) and it is subject to surveillance as specified in section 5 of Annex II. For class III devices, this certificate is valid only with the relevant EC Design-Examination Certificate of Annex II.4.

Reference to IMQ files Nos:
10AN00101; DM15A0468762-01; DM15A0544164-01; DM16E0653471-01; DM16-0004740-01; DM17-0015932-01; DM19-0037138-01.

Date:	2014-08-01
Updated:	2019-07-29
Substitution Date:	2018-01-15
Expiry Date:	2024-05-26

IMQ

EC CERTIFICATE

Certificate No 1694/MDD

Full Quality Assurance System Approval Certificate

This Approval Certificate is issued by IMQ S.p.A. as Notified Body for the Directive 93/42/EEC and its revised version. Notified Body notified to European Commission under number: 0051.

Date:	2014-08-01
Updated:	2019-07-29
Substitution Date:	2018-01-15
Expiry Date:	2024-05-26

IMQ

This Approval Certificate is subjected to the provisions laid down in the "IMQ regulation for the certification of Medical Devices - CE Marking - Directive 93/42/EEC".

This is a translation of the Italian text, which prevails in case of doubts

IMQ S.p.A. | I-20138 Milano | Via Quintiliano 43 | www.imq.it

CSQ

www.imq.it

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. / *CERTIFICATE N.* **9124.TRI2**

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

TRIDENT SRL

VIALE VITTORIO VENETO 6 - 20124 MILANO (MI)

UNITA' OPERATIVE / *OPERATIVE UNITS*

VIA ARTIGIANI 4 - 25014 CASTENEDOLO (BS)

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Progettazione, produzione e messa in commercio di apparecchiature radiologiche dentali ed accessori. Commercializzazione di sterilizzatrici per uso dentale
Design, production and placing on the market of dental X-ray equipment and accessories. Commercialization of sterilizers for dental use

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE

THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE *FIRST CERTIFICATION*	EMISSIONE CORRENTE *CURRENT ISSUE*	SCADENZA *EXPIRY*
	2015-06-04	2019-02-13	2021-06-04

IMQ S.p.A.- VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 005 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

La validità del certificato è subordinata a sorveglianza annuale e riesame completo del Sistema di Gestione con periodicità triennale
The validity of the certificate is submitted to annual audit and a reassessment of the entire Management System within three years

IMQ

Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 18 01 02745 005

Manufacturer:

Shanghai JPS Medical Co., Ltd.
Room 1805, Bldg 15
Lane 201, Jinxiang Rd
Pudong
201206 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

MedPath GmbH
Mies-van-der-Rohe-Strasse 8
80807 München
GERMANY

Product Category(ies):

Dental Units

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

Report No.: SH17127201

Valid from: 2018-05-16
Valid until: 2023-05-15

Date, 2018-05-16

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate
Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in Class IIa, IIb or III)

No. G2 18 01 02745 005

Facility(ies):

Shanghai JPS Medical Co., Ltd.
Room 1805, Bldg 15, Lane 201, Jinxiang Rd,
Pudong, 201206 Shanghai, PEOPLE'S REPUBLIC OF CHINA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q6 18 01 02745 006

Holder of Certificate: **Shanghai JPS Medical Co., Ltd.**
Room 1805, Bldg 15
Lane 201, Jinxiang Rd
Pudong
201206 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Shanghai JPS Medical Co., Ltd.
Room 1805, Bldg 15, Lane 201, Jinxiang Rd,
Pudong, 201206 Shanghai, PEOPLE'S
REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Production and Distribution of Dental Units, Medical Oil Free Air Compressor, Portable dental unit, Dental Suction System**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH17127201

Valid from: 2018-05-15
Valid until: 2021-05-14

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Date, 2018-05-15

Stefan Preiß

Page 1 of 1

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Deutsche Akkreditierungsstelle
D-ZM-11321-01-00