bsi.

By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 02118**

Issued To: **Metrex Research LLC**
28210 Wick Road
Romulus
Michigan 48174
USA

In respect of:

The manufacture of air-water syringe tips and disinfecting wipes for use with noninvasive medical instruments and non-invasive dental instruments.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1998-10-02** Date: **2020-10-27** Expiry Date: **2023-10-01**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 02118**
Date:	**2020-10-27**
Issued To:	**Metrex Research LLC** **28210 Wick Road** **Romulus** **Michigan 48174** **USA**

Subcontractor:	**Service(s) supplied**
Acot Plastics (Xiamen) Co. Ltd No. 2 Factory Building Development District Huli, Xiamen 361006 China	**Manufacture**
Kerr Corporation also trading as Pentron Clinical 1717 West Collins Ave. Orange California 92867 USA	**Regulatory Compliance**
Kerr Italia S.r.l. A subsidiary of Kerr Corporation Via Passanti, 332 Scafati Salerno 84018 Italy	**EU Representative**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 02118**
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Issued To:	**Metrex Research LLC** **28210 Wick Road** **Romulus** **Michigan 48174** **USA**

Subcontractor:	**Service(s) supplied**
Pak Technology 8000 West Good Hope Road Milwaukee, WI 53223 USA	**Crucial Supplier**
Rockline Industries PO Box 1007 1113 Maryland Ave. Sheboygan, WI 53081 USA	**Manufacture**
SDS de Mexico S. de R.L. de C.V., A Subsidiary of Ormco Corporation Circuito Sur No. 31 Parque Industrial Nelson Mexicali Baja California C.P.21395 Mexico	**Labelling** **Manufacture** **Packaging**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 02118**
Date:	**2020-10-27**
Issued To:	**Metrex Research LLC** **28210 Wick Road** **Romulus** **Michigan 48174** **USA**

Subcontractor:	**Service(s) supplied**
SpofaDental a.s. Markova 238 506 46 Jicin Czech Republic	**Manufacture**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 02118**
Date: **2020-10-27**
Issued To: **Metrex Research LLC**
28210 Wick Road
Romulus
Michigan 48174
USA

Date	Reference Number	Action
02 October 1998	-	First issue
01 October 2001	-	Certificate expiry
19 November 2004	-	Removal of the statement 'for activities related to recalls, vigilance reporting and technical file preparation'. Certificate renewal and reissue in new format
16 October 2008	-	Certificate renewal
26 April 2011	7632338	Company name change from 'Metrex Research Corporation', to 'Metrex Research LLC', extension to scope to include 'non-invasive'. and addition of 'Kerr Italia, S.r.l.' as EU Rep.
11 July 2012	7792763	Expansion of scope to include air-water syringe tips.
10 October 2013	8029719	Certificate renewal
28 March 2014	8136168	Addition of ACOT Plastics as subcontractor for Manufacturing
20 July 2016	8533492	Clarification of certificate scope to include "wipes". These are not a new product for Metrex, but prior scope did not clearly identify them.
01 November 2018	8923155	Certificate renewal. Removal of "sterilizing and disinfecting solutions and wipes" from scope. Addition of "Kerr Corporation" as subcontractor for regulatory activities.

By Royal Charter

EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 02118**
Date: **2020-10-27**
Issued To: **Metrex Research LLC**
28210 Wick Road
Romulus
Michigan 48174
USA

Date	Reference Number	Action
15 January 2019	7781009	Traceable to NB 0086.
18 March 2019	9737519	Re-instatement of disinfecting wipes to scope.
27 October 2020	3255354	Addition of Rockline Industries and Spofa Dental as subcontractors for manufacture of Caviwipe disinfecting wipes. Addition of Pak Technologies as Crucial Supplier of disinfecting solution.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
27 September 2021	3508492	Addition of subcontractor: SDS de Mexico S. de R.L de C.V, A subsidiary of Ormco Corporation for the activities of Labelling, Packaging and manufacture Circuito Sur No. 31, Parque Industrial Nelson Mexicali, Baja California, C.P.21395, Mexico

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Inspiring trust for a more resilient world.

27 September 2021

Metrex Research LLC
28210 Wick Road
Romulus
Michigan 48174
USA

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 02118	93/42/EEC Annex V	3508492	**Addition of subcontractors/suppliers –** SDS de Mexico S. de R.L de C.V, a subsidiary of Ormco Corporation for the activities of labelling, packaging and manufacture.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl

Metrex
INFECTION PREVENTION

Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Metrex Research, LLC
Manufacturer address and contact details	28210 Wick Road Romulus, MI 48174, USA
Single Registration Number (SRN) (if available)	Pending assignment by Ministry of Health

Authorised Representative name (if applicable)	Kerr Italia, S.r.l.
Authorised Representative address and contact details	Via Passanti, 174 Scafati (SA), 84018, Italy
Single Registration Number (SRN) (if available)	IT-MF-000007768

Notified body name (if applicable)	BSI	☒ See attached schedule
Notified body number (if applicable)	2797	☒ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	CE 02118	☒ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Metrex
INFECTION PREVENTION

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2023-10-01	☒ See attached schedule
End date of extended validity/transition period	2028-12-31	☒ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐Expired *before* 20 March 2023:

  ☐Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Metrex
INFECTION PREVENTION

☐Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

☒ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☒Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

Choose one applicable statement:

☒A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

Metrex
INFECTION PREVENTION

☐A QMS in accordance with Article 10(9) MDR is in place.

☒A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**
  - The device(s) continue to comply with the AIMDD or MDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Metrex Research, LLC

Company Name

12-Sep-2023 | 02:54 CEST

Brea, CA USA

Location **Date**

DocuSigned by:
Jennifer Evans
8DF30BE54382465...

Signature

Jennifer Evans

Name

Vice President, RA/QA Metrex

Title

jennifer.evans@envistaco.com

Contact Email

Metrex
INFECTION PREVENTION

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Surface Disinfectants (CaviWipes)	CE 02118	2023-10-01	BSI 2797	BSI 2797	2028-12-31	Not Applicable
Air/ Water Syringe Tips and associated adapters (Seal-Tight Tips and Adapters)	CE 02118	2023-10-01	BSI 2797	BSI 2797	2028-12-31	Not Applicable

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Metrex Research, LLC

28210 Wick Road

Romulus, MI 48174 USA

4-Jan-24

Notified Body Confirmation Letter

Reference: EU2023-607/649168

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, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Metrex Research, LLC

28210 Wick Road

Romulus, MI 48174 USA

SRN Number (if available): TBD Not issued yet by Italian Ministry of Health

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 the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (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/AIMDD 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 Mar 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 BSI Group The Netherlands B.V.,

Graeme Tunbridge
Senior Vice President, Medical Devices

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Device Name: Surface Disinfectants (CaviWipes) Canister Basic UDI-DI: 0615375000005QQ	Class IIa	Not Applicable	MDD EC Certificate: CE 02118 Expiry date: 2023-Oct-01 NB #: 2797
Device Name: Surface Disinfectants (CaviWipes) Flat Pack Basic UDI-DI: 0615375000004QN	Class IIa	Not Applicable	MDD EC Certificate: CE 02118 Expiry date: 2023-Oct-01 NB #: 2797
Air/ Water Syringe Tips (Seal-Tight Tips) Pouches Basic UDI-DI: 0615375000004QN	Class IIa	Not Applicable	MDD EC Certificate: CE 02118 Expiry date: 2023-Oct-01 NB #: 2797
Air/ Water Syringe Tips adapters (Seal-Tight Adapters) Auto-Lock Adapters Basic UDI-DI: 0615375000004QN	Class IIa	Not Applicable	MDD EC Certificate: CE 02118 Expiry date: 2023-Oct-01 NB #: 2797
Air/ Water Syringe Tips adapters (Seal-Tight Adapters) Quick Connect Adapter Basic UDI-DI: 0615375000004QN	Class IIa	Not Applicable	MDD EC Certificate: CE 02118 Expiry date: 2023-Oct-01 NB #: 2797
Air/ Water Syringe Tips adapters (Seal-Tight Adapters) Handpiece specific adapters Basic UDI-DI: 0615375000004QN	Class IIa	Not Applicable	MDD EC Certificate: CE 02118 Expiry date: 2023-Oct-01 NB #: 2797

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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/AIMDD device	MDD/AIMDD 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	Action
2024/01/04	Initial issue