

EC Certificate - Production Quality Assurance

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

No.**CE 02118****Issued To:**

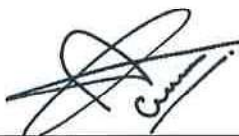
**Metrex Research LLC
28210 Wick Road
Romulus
Michigan 48174
USA**

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):



Albert Roossien, Regulatory Lead

First Issued: **1998-10-02**

Date: **2019-03-18**

Expiry Date: **2023-10-01**

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Page 1 of 1

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

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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:

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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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Certificate History

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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.

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Page 1 of 2

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Date	Reference Number	Action
15 January 2019	7781009	Traceable to NB 0086.
Current	9737519	Re-instatement of disinfecting wipes to scope.

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Page 2 of 2

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