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By Royal Charter

EC Certificate - Production Quality Assurance

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

No. **CE 615075**

Issued To: **Parker Laboratories, Inc.**
286 Eldridge Road
Fairfield
New Jersey
07004
USA

In respect of:

The manufacture of disinfectant Wipes and Spray and Sterile Ultrasound Transmission Gels. Those aspects of manufacture related to securing and maintaining the sterility of securement dressings.

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: **2014-09-05** Date: **2020-04-25** Expiry Date: **2024-05-26**

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Supplementary Information to CE 615075

Issued To:

Parker Laboratories, Inc.
286 Eldridge Road
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New Jersey
07004
USA

Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0101	Aquasonic 100 Sterile Ultrasound Gel	Not applicable for class IIa devices
MD 0108	Protex Pro disinfectant wipes and spray	Not applicable for class IIa devices
Class Is		
MD 0101	Ultradrape UGPIV Barrier and securement	Not applicable for class Is devices

First Issued: **2014-09-05** Date: **2020-04-25** Expiry Date: **2024-05-26**

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