bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

MedSafety Solutions
7012 S. Revere Pkwy, Suite 120
Centennial
Colorado
80112
USA

Holds Certificate No: **FM 680346**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, manufacture and distribution of non-sterile liquid dispensers and sterile transfer needles.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2018-03-06
Latest Revision Date: 2018-03-06

Effective Date: 2018-03-06
Expiry Date: 2021-03-05

...making excellence a habit.™

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.

bsi.

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 683245**

Issued To: **MedSafety Solutions**
7012 S. Revere Pkwy
Suite #120
Centennial
Colorado
80112
USA

In respect of:

The aspects of Annex II relating to securing and maintaining sterility in the manufacture of transfer needles

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Stewart Brain, Head of Compliance & Risk - Medical Devices

First Issued: **2018-02-07** Date: **2018-02-07** Expiry Date: **2023-02-06**

...making excellence a habit.™

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.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A member of BSI Group of Companies.