

Certificate US19/819943310

The management system of

Fort Defiance Industries LLC

2411 Maremont Parkway, Loudon, TN 37774 United States

has been assessed and certified as meeting the requirements of

ISO 13485:2016 EN ISO 13485:2016

For the following activities

Design and Manufacture of Sterilizers for the Medical Device Industry.

This certificate is valid from 09 December 2021 until 09 December 2024
and remains valid subject to satisfactory surveillance audits.
Recertification audit due a minimum of 60 days before the expiration date
Issue 2. Certified since 12 August 2019

Authorised by




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21HC 13485 2016 0421

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Certificate Number US19/81841407

The quality management system of

Fort Defiance Industries LLC

2411 Maremont Parkway, Loudon, TN, 37774, United States

Facility identification number : F003344

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate



MDSAP(ISO 13485:2016)



Canada:

Medical Devices Regulations -- Part 1 SOR 98/282

United States:

21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 -- Subparts A to D

For the following activities and devices

The Design and Manufacture of Sterilizers for the Medical Device Industry.

This certificate is valid from
Effective Date: 2022-01-24 until Expiry Date: 2024-12-09
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2024-11-12

Issue 2. Certified since 2019-02-20

Authorised by L.Henderson
Business Manager

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