

Certificate US21/819944379

The management system of

Integra Biotechnical, S.A. de C.V. (A Subsidiary of Amphenol Critical Medical Technologies LLC)

Privada Los Pinos # 17030, Interior 3, Colonia Niños Héroes, Este, CP 22120, Tijuana Baja California, México.

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

Contract manufacture of non-active medical devices and components of blood drawable sets, transducer arrays, infusion sets, waste management sets, eye surgery handpiece devices, respiratory circuits, negative pressure wound therapy sets for general use, cryogenic surgical devices, disposable bloodline sets, cable assemblies, and kit assembly for medical procedures. Contract manufacturing of plastic injection molded components for non-active medical devices.

This certificate is valid from 02 December 2024 until 18 May 2027 and remains valid subject to satisfactory surveillance audits.

Issue 5. Certified since 18 May 2021

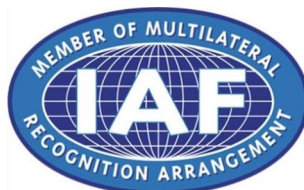
Certified activities performed by additional sites are listed on subsequent pages.

L. Moran

Authorised by

Liz Moran
Business Manager

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Certificate US21/819944379, continued

Integra Biotechnical, S.A. de C.V. (A Subsidiary of Amphenol Critical Medical Technologies LLC)

ISO 13485:2016

EN ISO 13485:2016

Issue 5

Sites

Integra Biotechnical, S.A. de C.V. (A Subsidiary of Amphenol Critical Medical Technologies LLC)
Privada Los Pinos # 17030, Interior 3, Colonia Niños Héroes, Este, CP 22120, Tijuana Baja California, México.
Contract Manufacturing of non-sterile cables.

Integra Biotechnical, S.A. de C.V. (A Subsidiary of Amphenol Critical Medical Technologies LLC)
Privada Los Pinos # 17030, Interior 15, 16 y 17 Colonia Niños, Héroes Este, CP 22120, Tijuana Baja California, México.

Contract manufacture of non-active medical devices and components of blood drawable sets, transducer arrays infusion sets, medical use kits supplies (syringes, markers, tubing), waste management set, eye surgery handpiece devices, respiratory circuit, negative pressure wound, therapy sets for general use, cryogenic surgical devices, disposable bloodline sets.

Integra Biotechnical, S.A. de C.V. (A Subsidiary of Amphenol Critical Medical Technologies LLC)
Andador Antigua Tecate # 16780, Interior 65 y 66 Colonia Niños, Héroes Este, CP 22120, Tijuana, Baja California, México.

Contract manufacturing and assembly of plastic injection molded components for medical devices.



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