



Certificate US21/819944379

The management system of

Integra Biotechnical, S.A. de C.V. (A Subsidiary of Carlisle 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 design and 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 31 October 2023 until 18 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 18 May 2021

Organization certified since 30 December 1899 and first certified by SGS on 18 May 2021.

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

Authorised by
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Global Head - Certification Services

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

ISO 13485:2016

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Issue 3
Sites
Integra Biotechnical, S.A. de C.V. (A Subsidiary of Carlisle Medical Technologies, LLC) Privada Los Pinos # 17030, Interior 3, Colonia Niños Héroes, Este, CP 22120, Tijuana Baja California, México.
Manufacturing and assembly of cables.
Integra Biotechnical, S.A. de C.V. (A Subsidiary of Carlisle Medical Technologies, LLC) Privada Los Pinos # 17030, Interior 15, 16 y 17 Colonia Niños, Héroes Este, CP 22120, Tijuana Baja California, México.
Contract design and 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 Carlisle 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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