















Auditing Organization Availability to Conduct MDSAP Audits

The organizations listed below submitted an application to the Medical Device Single Audit Program (MDSAP). The table specifies their status regarding their application, their authorization to conduct MDSAP audits, and their recognition.

| Eligible Auditing Organization | Location | Contact | Application Received | Authorized to Conduct MDSAP Audits | Recognition |
|--|--|--|--|--|--|
|  | <p>BSI Group America Inc. 12950 Worldgate Drive, Suite 800, Herndon, VA 20170 USA http://www.bsigroup.com/en-US/</p> <p>Critical Location Milton Keynes, UK</p> | <p>Patricia Murphy patricia.murphy@bsigroup.com +1 571 291 5726</p> | <p style="text-align: center;">Yes</p> | <p style="text-align: center;">Yes</p> | <p style="text-align: center;">Yes</p> |
|  | <p>DEKRA Certification B.V. Meander 1051 Arnhem, 6825 MJ Netherlands http://www.dekra.com/en/home</p> <p>Critical Locations North Wales, PA, USA Concord, CA, USA</p> | <p>Brent Anderson Brent.Anderson@dekra.com +1 925 283 7535</p> | <p style="text-align: center;">Yes</p> | <p style="text-align: center;">Yes</p> | <p style="text-align: center;">Yes</p> |

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|--|--|---|----------------------|------------------------------------|-------------|
|  | <p>DQS Medizinprodukte GmbH August-Schanz-Strasse 21 D-60433 Frankfurt am Main Germany http://www.dqs-medizinprodukte.de/en</p> <p>Operating from DQS Medizinprodukte GmbH Konrad-Adenauer-Allee 8 D-61118 Bad Vilbel, Germany</p> | <p>Szymon Kurdyn Szymon.Kurdyn@dqs-med.de +49 69 95427-507 +49 69 95427-6507</p> | Yes | Yes | Yes |
|  | <p>Intertek Testing Services NA Inc. 900 Chelmsford Street Suite 301-3 Lowell, MA 01851 USA www.intertek.com</p> | <p>Christine Forcier Christine.Forcier@intertek.com +1 514-378-6418</p> | Yes | Yes | Yes |
|  | <p>Laboratoire National de métrologie et d'Essais (LNE) - Division certification G-MED (trading as LNE/G-MED and G-MED) 1, rue Gaston Boissier 75724 Paris, Cedex 15 France http://www.gmed.fr</p> <p>Critical Locations St. Etienne, France Bethesda, MD, USA</p> | <p>Corinne Delorme Corinne.Delorme@lne.fr +33 1 40 43 39 72 +33 1 40 43 37 37</p> | Yes | Yes | Yes |

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|---|---|---|----------------------|------------------------------------|-------------|
|  | <p>Lloyd's Register Quality Assurance Inc. 1330 Enclave Parkway, Suite 200 Houston, TX 77077 USA http://www.lrgausa.com</p> <p>Critical Location Birmingham, UK</p> | <p>Krissi Temple Krissi.Temple@lrqa.com +1 281 398 7370 +1 281 398 7337</p> | Yes | Yes | No |
|  | <p>National Standards Authority of Ireland 1 Swift Square, Northwood, Santry, Dublin 9, Ireland D09 A0E4</p> <p>Operating from: NSAI, Inc. 20 Trafalgar Square, Suite 603 Nashua, NH 03063 USA http://www.NSAIinc.com</p> | <p>Eoin Banville Eoin.Banville@nsaiinc.com +1 (603) 882-4412</p> | Yes | Yes | Yes |
|  | <p>NSF Health Sciences Certification, LLC 1701 Pennsylvania Avenue NW Suite 300 Washington, DC 20006 USA www.nsf.org</p> | <p>Brian Ludovico bludovico@nsf.org +1 (202) 821-4147</p> | Yes | Yes | No |
|  | <p>QMI-SAI Canada Limited 20 Carlson Court, Suite 200 Toronto, ON, M9W 7K6 http://www.qmi.com</p> | <p>Zaher Kharboutly zaher.kharboutly@saiglobal.com +1 (416) 276-9525</p> | Yes | Yes | No |

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|---|--|---|----------------------|------------------------------------|-------------|
|  | <p>SGS United Kingdom Ltd. Rossmore Business Park Ellesmere Port, Cheshire CH65 3EN</p> <p>Operating from SGS United Kingdom Ltd. Unit 202B, Worle Parkway Weston Super Mare, Somerset BS22 6WA United Kingdom http://www.sgs.co.uk/</p> | <p>Timothy D. Gooch timothy.gooch@sgs.com +1 (256) 763-3099</p> | <p>Yes</p> | <p>Yes</p> | <p>Yes</p> |
|  | <p>TÜV Rheinland of North America, Inc. 12 Commerce Road Newtown, CT 06570 USA</p> <p>Operating from : TÜV Rheinland of North America, Inc. 1279 Quarry Lane, Suite A and C Pleasanton, CA 94566 USA www.tuv.com</p> <p>Critical Locations Köln, Germany Shanghai, China</p> | <p>Zina Apostolou-Keiper ZApostolou@us.tuv.com +1 (925) 249-9123 x2154</p> | <p>Yes</p> | <p>Yes</p> | <p>Yes</p> |
|  | <p>TÜV SUD America Inc. (also operating as TÜV America Inc.) 10 Centennial Drive Peabody, MA 01960 USA http://www.tuv-sud-america.com/</p> <p>Critical Location Munich, Germany</p> | <p>Dawn Tibodeau DTibodeau@tuvam.com +1 651 638 0288 +1 651 638 0295</p> | <p>Yes</p> | <p>Yes</p> | <p>Yes</p> |

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|  | <p>TUV USA, Inc. 215 Main Street, Suite 3 Salem, NH 03079 USA http://www.tuv-nord.com/us</p> | <p>Ralf Thomsen RThomsen@tuv-nord.com +1 603 870 8023 +1 603 870 8026</p> | <p>Yes</p> | <p>Yes</p> | <p>Yes</p> |
|  | <p>UL Medical and Regulatory Services UL, LLC 333 Pfingsten Road Northbrook IL 60062-2096 USA</p> <p>Operating from UL, LLC 47173 Benicia Street Fremont, CA USA</p> | <p>Michael J. Windler Michael.J.Windler@ul.com +1 847-664-3409</p> | <p>Yes</p> | <p>Yes</p> | <p>Yes</p> |