

MDSAP Regulatory Authority Contact Information

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| <p style="text-align: center;">AUSTRALIA – TGA</p> <p style="text-align: center;">MDSAP@tga.gov.au</p> | <ul style="list-style-type: none"> • Medical Device Single Audit Program (MDSAP) Medical Devices Branch (MDB) Therapeutic Goods Administration (TGA) Department of Health PO Box 100, Woden, ACT 2606 Australia |
| <p style="text-align: center;">BRAZIL – ANVISA</p> <p style="text-align: center;">MDSAP.ATENDIMENTO@ANVISA.GOV.BR</p> | <ul style="list-style-type: none"> • Anvisa – Agência Nacional de Vigilância Sanitária Setor de Indústria e Abastecimento (SIA) - Trecho 5, Área Especial 57 / Lote 200 Brasília (DF) – Brazil POSTAL CODE: 71205-050 |
| <p style="text-align: center;">CANADA – HC</p> <p style="text-align: center;">QS_MDB_HC@hc-sc.gc.ca</p> | <ul style="list-style-type: none"> • Quality Systems Division Medical Devices Bureau 2934 Baseline Road Qualicum, Tower B Ottawa, Ontario, Canada K1A 0K9 Address Locator: 3403A |
| <p style="text-align: center;">JAPAN – PMDA</p> <p style="text-align: center;">MDSAP@pmda.go.jp</p> | <ul style="list-style-type: none"> • Japan’s Ministry of Health, Labour and Welfare Ministry of Health, Labour and Welfare Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau 1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo 1008616 Japan • Pharmaceuticals and Medical Devices Agency Office of Manufacturing/Quality and Compliance- Division of Registered Certification Body Assessment Shin-kasumigaseki Bldg. 3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan |
| <p style="text-align: center;">US – FDA</p> <p style="text-align: center;">MDSAP@FDA.HHS.GOV</p> | <ul style="list-style-type: none"> • US FDA – Food and Drug Administration Center for Devices and Radiological Health Office of Product Evaluation and Quality Office of Regulatory Programs – DRP2: Division of Establishment Support 10903 New Hampshire Avenue Building 66 Silver Spring, MD 20993-0002 Tel.: 301-796-5545 |