| smiths medical<br>bringing technology to life | **Declaration of Conformity**<br>TD-1066: Invasive Patient Pressure Monitoring Devices and Accessories | DoC-1066<br>Revision Number: 101 |
|---|---|---|

| | |
|---|---|
| **Legal Manufacturer:** | Smiths Medical ASD Inc.<br>6000 Nathan Lane North<br>Minneapolis, MN 55442 USA |
| **Single Registration Number (SRN):** | US-MF-000002566 |
| **EU Authorized Representative:** | Smiths Medical Czech Republic a. s.<br>Olomoucká 306<br>Hranice 1 – Město,<br>753 01 Hranice, Czech Republic |
| **Single Registration Number (SRN):** | CZ-AR-000002443 |
| **Product Tradename(s):** | Medex™, Logical®, TranStar®, NovaTrans® |
| **Conformity Assessment Route:** | Annex II and Annex III |
| **Notified Body:** | N/A Class I Self Certified |
| **EC Certificate Number:** | N/A Class I Self-Certified |

Smiths Medical ASD, Inc. hereby declares under its sole responsibility that the product(s) referenced conform to the relevant provisions of the European Union Council Directive 2017/745 on Medical Devices (MDR).

**Authorized Signatory:**

Signature: _____ Date: 15 July 2021

Name: LeeAnne Swiridow

Title: Regulatory Affairs Director

Location of Signatory: Minneapolis, MN, USA

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**Appendix 1: Product List**

| No. | Catalog Number | Product Description | Basic UDI-DI | EU Risk Class | EU Rule |
|---|---|---|---|---|---|
| 1. | MX260CZ | Clamp-DPS for 1 Transducer | 0610586M0378DY | Ins/nm | 1 |
| 2. | MX260-PMCZ | LogiCal Patient Mount | 0610586M0378DY | Ins/nm | 1 |
| 3. | MX261P1CZ | Clamp-DPS for Bracket | 0610586M0378DY | Ins/nm | 1 |
| 4. | MX262P1CZ | Bracket-DPS for 2 Transducers | 0610586M0378DY | Ins/nm | 1 |
| 5. | MX263P1CZ | Bracket-DPS for 3 Transducers | 0610586M0378DY | Ins/nm | 1 |
| 6. | MX264CZ | Bracket-DPS for 4 Transducers | 0610586M0378DY | Ins/nm | 1 |
| 7. | MX267C2CZ | LogiCal Bracket | 0610586M0378DY | Ins/nm | 1 |
| 8. | MX1821-BCZ | C-Fusor Squeeze Bulb | 0610586M0167DH | Ins/nm | 1 |
| 9. | MX1821-GCZ | C-Fusor Pressure Gauge | 0610586M0167DH | Ins/nm | 1 |
| 10. | MX240P1CZ | Manifold Horizontal | 0610586M0378DY | Ins/nm | 1 |
| 11. | MX244P1CZ | Clamp For 1/2" Pole | 0610586M0378DY | Ins/nm | 1 |
| 12. | MX4705P1CZ | Cuff Clear 500ML | 0610586M0351DC | Ins/nm | 1 |
| 13. | MX4710P1CZ | Cuff Clear 1000ML | 0610586M0351DC | Ins/nm | 1 |
| 14. | MX4805P1CZ | Pressure Infusor C Fusor 500ML Bag | 0610586M0167DH | Ins/nm | 1 |
| 15. | MX4806CZ | C-Fusor Replacement Bag 500ML | 0610586M0167DH | Ins/nm | 1 |
| 16. | MX4810P1CZ | Pressure Infusor C Fusor 1000ML Bag | 0610586M0167DH | Ins/nm | 1 |
| 17. | MX4830P1CZ | Extension on MX4810 | 0610586M0351DC | Ins/nm | 1 |
| 18. | MX800P1CZ | Modular Transducer Plate | 0610586M0378DY | Ins/nm | 1 |

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| No. | Catalog Number | Product Description | Basic UDI-DI | EU Risk Class | EU Rule |
|---|---|---|---|---|---|
| 19. | MX800-SCZ | Novastrap | 0610586M0378DY | Ins/nm | 1 |
| 20. | MX257C2CZ | Transtar Bracket | 0610586M0378DY | Ins/nm | 1 |
| 21. | MX961Y08 | Single Line for Siemens 4th Generation | 0610586M0123CV | Ins/nm | 1 |
| 22. | MX962Z02P1 | Two Gang for Hp 12 Pin Merlin | 0610586M0123CV | Ins/nm | 1 |
| 23. | MX962Z42P1CZ | Two Gang for Spacelabs, Protocal, Critikon | 0610586M0123CV | Ins/nm | 1 |
| 24. | MX962Z50P1CZ | 2 Gang w/o Plug | 0610586M0123CV | Ins/nm | 1 |
| 25. | MX962Z02STCZ | Two Gang for Hp 12 Pin Merlin | 0610586M0123CV | Ins/nm | 1 |
| 26. | MX962Z03P1CZ | Two Gang for Physio Control | 0610586M0123CV | Ins/nm | 1 |
| 27. | MX962Z04P1CZ | Two Gang for Datascope/Kontron | 0610586M0123CV | Ins/nm | 1 |
| 28. | MX962Z14P1CZ | Cable Two Gang for Mennen | 0610586M0123CV | Ins/nm | 1 |
| 29. | MX962Z15P1CZ | Two Gang for Marquette M 7000 | 0610586M0123CV | Ins/nm | 1 |
| 30. | MX962Z17P1CZ | Two Gang for S & W. Narco/Airshields | 0610586M0123CV | Ins/nm | 1 |
| 31. | MX962Z20P1CZ | Two Gang for Datex | 0610586M0123CV | Ins/nm | 1 |
| 32. | MX962Z22P1CZ | Two Gang for Nihon Kohde N | 0610586M0123CV | Ins/nm | 1 |
| 33. | MX962Z62P1CZ | Two Gang for Datex | 0610586M0123CV | Ins/nm | 1 |
| 34. | MX962Z64P1CZ | Fukuda Denshi | 0610586M0123CV | Ins/nm | 1 |
| 35. | MX962Z68P1CZ | Two Gang for Marquette T Ram | 0610586M0123CV | Ins/nm | 1 |
| 36. | MX962Z70P1CZ | Two Gang for PPG Midas | 0610586M0123CV | Ins/nm | 1 |
| 37. | MX962Z74P1CZ | Two Gang for Bard | 0610586M0123CV | Ins/nm | 1 |

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| No. | Catalog Number | Product Description | Basic UDI-DI | EU Risk Class | EU Rule |
|---|---|---|---|---|---|
| 38. | MX963Y08CZ | Three Gang for Siemens 4th Generation | 0610586M0123CV | Ins/nm | 1 |
| 39. | MX963Y132CZ | Triple Logical Cable for Witt Biomedical | 0610586M0123CV | Ins/nm | 1 |
| 40. | MX963Z04P1CZ | Three Gang for Datascope /Kontron | 0610586M0123CV | Ins/nm | 1 |
| 41. | MX963Z15P1CZ | Three Gang for Marquette M7000 | 0610586M0123CV | Ins/nm | 1 |
| 42. | MX963Z20P1CZ | Three Gang for Datex | 0610586M0123CV | Ins/nm | 1 |
| 43. | MX963Z22P1CZ | Three Gang for Nihon Kohden | 0610586M0123CV | Ins/nm | 1 |
| 44. | MX963Z42P1CZ | Three Gang for Spacelabs, Protocal, Critik | 0610586M0123CV | Ins/nm | 1 |
| 45. | MX963Z50P1CZ | Three Gang w/o Plug | 0610586M0123CV | Ins/nm | 1 |
| 46. | MX963Z68P1CZ | Logical 3 Channel Cable Marquette Tram | 0610586M0123CV | Ins/nm | 1 |
| 47. | MX964Y08CZ | Four Gang for Siemens 4th Generation | 0610586M0123CV | Ins/nm | 1 |
| 48. | MX964Z02P1CZ | Four Gang for Hp 12 Pin Merlin | 0610586M0123CV | Ins/nm | 1 |
| 49. | MX964Z20P1CZ | Four Gang for Datex | 0610586M0123CV | Ins/nm | 1 |
| 50. | MX964Z22P1CZ | Four Gang for Nihon Kohden | 0610586M0123CV | Ins/nm | 1 |
| 51. | MX964Z50P1CZ | Four Gang w/o Plug (10"/10"+15") | 0610586M0123CV | Ins/nm | 1 |
| 52. | MX964Z85CZ | Four Gang Cable for Medos Hlm Deltastream | 0610586M0123CV | Ins/nm | 1 |
| 53. | MX980-02CZ | Cable Hp 12 Pin | 0610586M0125CZ | Ins/nm | 1 |
| 54. | MX980-04CZ | Transtar Cable for Datascope/Kontron | 0610586M0125CZ | Ins/nm | 1 |
| 55. | MX980-14CZ | Transtar Cable for Mennen | 0610586M0125CZ | Ins/nm | 1 |
| 56. | MX980-17CZ | Transtar Cable for S&W Narco/Airshields | 0610586M0125CZ | Ins/nm | 1 |

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| No. | Catalog Number | Product Description | Basic UDI-DI | EU Risk Class | EU Rule |
|---|---|---|---|---|---|
| 57. | MX980-20CZ | Transtar Cable for Datex | 0610586M0125CZ | Ins/nm | 1 |
| 58. | MX980-42CZ | Cable for Space Lab | 0610586M0125CZ | Ins/nm | 1 |
| 59. | MX980-50CZ | Cable Universal | 0610586M0125CZ | Ins/nm | 1 |
| 60. | MX980-62CZ | Transtar Cable for Datex | 0610586M0125CZ | Ins/nm | 1 |
| 61. | MX981-105CZ | Transtar Cable for Schwarzer Cardis 5000 | 0610586M0125CZ | Ins/nm | 1 |
| 62. | MX981-132CZ | Cable: Transtar Witt Monitor Series | 0610586M0125CZ | Ins/nm | 1 |
| 63. | MX981-15CZ | Cable for Marquette | 0610586M0125CZ | Ins/nm | 1 |
| 64. | MX981-19CZ | Cable: Handwired | 0610586M0125CZ | Ins/nm | 1 |
| 65. | MX981-22CZ | Cable: Handwired | 0610586M0125CZ | Ins/nm | 1 |
| 66. | MX981-37CZ | Cable:P.P.G.RM300 | 0610586M0125CZ | Ins/nm | 1 |
| 67. | MX981-44CZ | Cable for Kontron Kaat | 0610586M0125CZ | Ins/nm | 1 |
| 68. | MX981-47CZ | Cable for Quinton Q Cath 5 Pin Male | 0610586M0125CZ | Ins/nm | 1 |
| 69. | MX981-64CZ | Cable for Fukuda | 0610586M0125CZ | Ins/nm | 1 |
| 70. | MX981-68CZ | Cable for Marquette Tram | 0610586M0125CZ | Ins/nm | 1 |
| 71. | MX981-69CZ | Transtar Interface Cable for Sarns Monitor | 0610586M0125CZ | Ins/nm | 1 |
| 72. | MX900-02CZ | Cable for H-P 12 Pin | 0610586M0108CZ | Ins/nm | 1 |
| 73. | MX900-04CZ | Cable for Datascope & Kontron | 0610586M0108CZ | Ins/nm | 1 |
| 74. | MX901-08CZ | Cable for Siemens 4th Generation | 0610586M0108CZ | Ins/nm | 1 |
| 75. | MX901-19CZ | Cable for Siemens SI | 0610586M0108CZ | Ins/nm | 1 |

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| No. | Catalog Number | Product Description | Basic UDI-DI | EU Risk Class | EU Rule |
|---|---|---|---|---|---|
| 76. | MX901-68CZ | Cable for Marquette Tran 200 | 0610586M0108CZ | Ins/nm | 1 |
| 77. | MX901-74CZ | Novatrans Cable for Bard | 0610586M0108CZ | Ins/nm | 1 |
| 78. | MX901-105CZ | Novatrans Cable for Schwarzer Cardis 5000 | 0610586M0108CZ | Ins/nm | 1 |
| 79. | MX901-132CZ | Cable: Novatrans Witt Monitor Series 4 Front | 0610586M0108CZ | Ins/nm | 1 |
| 80. | MX961Y05CZ | Single Line for Honeywell (E for M) | 0610586M0123CV | Ins/nm | 1 |
| 81. | MX961Y08L1CZ | Single Line for Siemens SC 9000 | 0610586M0123CV | Ins/nm | 1 |
| 82. | MX961Y08L2CZ | Single Line for Siemens SC9000 | 0610586M0123CV | Ins/nm | 1 |
| 83. | MX961Y08L20CZ | Single Line for Siemens 6 Metres | 0610586M0123CV | Ins/nm | 1 |
| 84. | MX961Y118CZ | Cable: Single Line for Dantec | 0610586M0123CV | Ins/nm | 1 |
| 85. | MX961Y126CZ | LogiCal Cable for Scholar Vital Signs Mon | 0610586M0123CV | Ins/nm | 1 |
| 86. | MX961Y130CZ | LogiCal Cable for Biotronik EP Control | 0610586M0123CV | Ins/nm | 1 |
| 87. | MX961Y132CZ | Single LogiCal Cable for Witt Biomedical | 0610586M0123CV | Ins/nm | 1 |
| 88. | MX961Y19CZ | Single Line for Siemens Mingograph | 0610586M0123CV | Ins/nm | 1 |
| 89. | MX961Y19L20CZ | Single Line for Siemens Mingograph (20FT) | 0610586M0123CV | Ins/nm | 1 |
| 90. | MX961Y44CZ | Single Line for Kontron Kaat | 0610586M0123CV | Ins/nm | 1 |
| 91. | MX961Y68L20CZ | Single Line for Marquette Tram (20FT) | 0610586M0123CV | Ins/nm | 1 |
| 92. | MX961Y79CZ | Single Line for Jostra Hlm | 0610586M0123CV | Ins/nm | 1 |
| 93. | MX961Y80CZ | Cable Single Line for Prucka Cardiolab EP | 0610586M0123CV | Ins/nm | 1 |
| 94. | MX961Z01P1CZ | Cable Logical Hewlet Packard Twinax | 0610586M0123CV | Ins/nm | 1 |

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| No. | Catalog Number | Product Description | Basic UDI-DI | EU Risk Class | EU Rule |
|---|---|---|---|---|---|
| 95. | MX961Z03P1CZ | Single Line for Physio Control | 0610586M0123CV | Ins/nm | 1 |
| 96. | MX961Z04P1CZ | Single Line for Datascope/Kontron | 0610586M0123CV | Ins/nm | 1 |
| 97. | MX961Z14P1CZ | Single Line for Mennen | 0610586M0123CV | Ins/nm | 1 |
| 98. | MX961Z13P1CZ | Single Line for Hellige (Servomed) | 0610586M0123CV | Ins/nm | 1 |
| 99. | MX961Z15P1CZ | Single Line for Marquette M7000 | 0610586M0123CV | Ins/nm | 1 |
| 100. | MX961Z17P1CZ | Single Line for S & W. Narco/Airshields | 0610586M0123CV | Ins/nm | 1 |
| 101. | MX961Z19P1CZ | Single Line for Siemens Mingograph | 0610586M0123CV | Ins/nm | 1 |
| 102. | MX961Z22P1CZ | Single Line for Nihon Kohden | 0610586M0123CV | Ins/nm | 1 |
| 103. | MX961Z25P1CZ | Single Logical Cable Corometrics | 0610586M0123CV | Ins/nm | 1 |
| 104. | MX961Z34P1CZ | Cable for HP Fetal Monitor | 0610586M0123CV | Ins/nm | 1 |
| 105. | MX961Z42P1CZ | Single Line for Spacelabs, Protocal, Criti | 0610586M0123CV | Ins/nm | 1 |
| 106. | MX961Z44P1CZ | Single Line for Kontron Kaat | 0610586M0123CV | Ins/nm | 1 |
| 107. | MX961Z47P1CZ | Single Line for Quinton Q-Cath. | 0610586M0123CV | Ins/nm | 1 |
| 108. | MX961Z50P1CZ | Single Line w/o Plug (12 ') | 0610586M0123CV | Ins/nm | 1 |
| 109. | MX961Z62P1CZ | Single Line for Datex | 0610586M0123CV | Ins/nm | 1 |
| 110. | MX961Z64P1CZ | Fukuda Denshi | 0610586M0123CV | Ins/nm | 1 |
| 111. | MX961Z68P1CZ | Single Line for Marquette Tram | 0610586M0123CV | Ins/nm | 1 |
| 112. | MX961Z74P1 | Single Line for Bard | 0610586M0123CV | Ins/nm | 1 |
| 113. | MX961Z86CZ | LogiCal Cable for Cardiotek EP Tracer | 0610586M0123CV | Ins/nm | 1 |

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| No. | Catalog Number | Product Description | Basic UDI-DI | EU Risk Class | EU Rule |
|---|---|---|---|---|---|
| 114. | MX962Y100CZ | Logical Double Line for Bruker | 0610586M0123CV | Ins/nm | 1 |
| 115. | MX962Y118CZ | Cable: Double Line for Dantec | 0610586M0123CV | Ins/nm | 1 |
| 116. | MX962Y126CZ | Cable for Scholar | 0610586M0123CV | Ins/nm | 1 |
| 117. | MX962Y132CZ | Double Logical Cable for Witt Biomedical | 0610586M0123CV | Ins/nm | 1 |
| 118. | MX962Y19CZ | Two Gang for Siemens Mingograph | 0610586M0123CV | Ins/nm | 1 |
| 119. | MX981-100 | Kabel Transtar F.Bruker | 0610586M0125CZ | Ins/nm | 1 |
| 120. | MX961Y68STCZ | Single Line for Marquette Tram | 0610586M0123CV | Ins/nm | 1 |
| 121. | MX961Z02STCZ | Single Line for HP 12 PI N Merlin | 0610586M0123CV | Ins/nm | 1 |
| 122. | MX962Y08STCZ | Two Gang for Siemens 4th Generation | 0610586M0123CV | Ins/nm | 1 |
| 123. | MX961Y100 | KABEL LOGICAL 1FACH F. BRUKER 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 124. | MX961Y102 | LOGICAL CABLE FOR SCHILLER PB1000 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 125. | MX961Y104 | LOGICAL CABLE FOR F.SCHWARZER/MADAUS 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 126. | MX961Y105 | SINGLE LINE FOR SCHWARZER/MADAUS NEW 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 127. | MX961Y109 | LOGICAL KABEL FUER DRAEGER HEMOPOD 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 128. | MX961Y110 | LOGICAL INTERFACE CABLE, 1FOLD, FOR MAQUET 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 129. | MX961Y116 | SINGLE LINE FOR STOCKERT LOGICAL | 0610586M0123CV | Ins/nm | 1 |
| 130. | MX961Y117 | LOGICAL CABLE FOR ARROW ACAT 1 | 0610586M0123CV | Ins/nm | 1 |
| 131. | MX961Y120 | LOGICAL CABLE FOR MIRACOR PICSO IMPULSE CONSOLE, CSP 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 132. | MX961Y123 | LOGICAL CABLE FOR MIRACOR PICSO® IMPULSE CONSOLE, AP 1/EA | 0610586M0123CV | Ins/nm | 1 |

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| No. | Catalog Number | Product Description | Basic UDI-DI | EU Risk Class | EU Rule |
|---|---|---|---|---|---|
| 133. | MX961Y127 | SINGLE CABLE FOR LOGICAL DAVID/METEK REFER 1.12 | 0610586M0123CV | Ins/nm | 1 |
| 134. | MX961Y37 | SINGLE LINE FOR DRAGER M ONITORS | 0610586M0123CV | Ins/nm | 1 |
| 135. | MX961Y68 | KABEL LOGICAL EINFACH F. MARQUETTE TRAM 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 136. | MX961Y69 | SINGLE CABLE FOR 3M (SARNS) AND JOSTRA 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 137. | MX961Y77 | SINGLE LINE FOR SIEMENS SC6000 | 0610586M0123CV | Ins/nm | 1 |
| 138. | MX961Y88 | KABEL FÜR -88 MONITOR CENTRIMAG, FIRMA LEVITRONIX 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 139. | MX961Y91 | LOGICAL KABEL FÜR CORPULS 08/16 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 140. | MX961Z02P1 | SINGLE LINE FOR HP 12 PIN MERLIN 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 141. | MX961Z20P1 | SINGLE LINE FOR DATEX | 0610586M0123CV | Ins/nm | 1 |
| 142. | MX961Z85 | EINFACH LOGICAL CABLE FOR MEDOS PUMP 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 143. | MX961Z94 | EINFACH LOGICAL-KABEL FÜR CORPULS C3 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 144. | MX961Z96 | EINFACHKABEL LOGICAL FÜR MEDRAD "VERIS" MONITOR 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 145. | MX962Y08 | TWO GANG FOR SIEMENS 4TH GENERATION | 0610586M0123CV | Ins/nm | 1 |
| 146. | MX962Y102 | KABEL LOGICAL ZWEIFACH F.SCHILLER PB1000 | 0610586M0123CV | Ins/nm | 1 |
| 147. | MX962Y105 | 2 GANG FOR SCHWARZER/MADAUS NEW | 0610586M0123CV | Ins/nm | 1 |
| 148. | MX962Y127 | LOGICAL ZWEIFACHKABEL FÜR DAVID / METEK 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 149. | MX962Y13 | TWO GANG FOR HELLIGE (SE RVOMED) | 0610586M0123CV | Ins/nm | 1 |
| 150. | MX962Y134 | DOUBLE LOGICAL CABLE FOR HAEMOBOX | 0610586M0123CV | Ins/nm | 1 |
| 151. | MX962Y37 | TWO GANG FOR DRAGER MONI TORS | 0610586M0123CV | Ins/nm | 1 |

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| No. | Catalog Number | Product Description | Basic UDI-DI | EU Risk Class | EU Rule |
|---|---|---|---|---|---|
| 152. | MX962Y68 | TWO GANG FOR MARQUETTE T RAM 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 153. | MX962Y77 | TWO GANG FOR SIEMENS SC6000 | 0610586M0123CV | Ins/nm | 1 |
| 154. | MX962YDAVID | KABEL LOGICAL 2FACH F.DAVID / METEK 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 155. | MX962Z80P1 | LOGICAL 2 CHANNEL CABLE : PRUCKA CARDIOLAB 1/EA | 0610586M0123CV | Ins/nm | 1 |
| 156. | MX963Y116 | KABEL LOGICAL DREIFACH FÜR STOECKERT HLM 1/EA | 0610586M0123CV | Ins/nm | 1 |

**Appendix 2: Revision History**

| Revision Number | Summary of Changes / Additions | Created / Revised by | Date |
|---|---|---|---|
| 100 | Initial release of MDR DoC-1066 to meet MDR DoA (Date of Application) requirements for Class I devices. SKU's were migrated from MDD DoC-255 and DoC-089. | Dominique Neisz | 19-MAY-2021 |
| 101 | Correction of LM SRN number and addition of EC Rep SRN number. Change of Signatory to LeeAnne Swiridow. | Ashley Levang | 06-JUL-2021 |

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