Labcorp Bedford, LLC **Fiscal Year 2022**

Annual Report of Research Facility
Column E Explanation Form

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1. **Registration Number:** 14-R-0101

2. **Research Facility Headquarters address:** 15 Wiggins Ave Bedford, MA 01730

3. **Number of animals used in the study:** 4748

4. **Specie (common name) of animals used in this study(s).** Guinea Pig

5. **Explain the procedure producing pain and/or distress.** (b) (4) [redacted]

6. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.**

   (b) (4) [redacted]

7. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR 113.102):**

   FDA, CDRH, June 16, 2016, Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluations and testing within a risk management process”

   ISO 10993-10, 2006, Biological Evaluation of Medical Devices – Part 10: Tests for Skin Sensitization.

   ISO 10993-12, 2021. Biological Evaluation of Medical Devices – Part 12: Sample Preparation Reference Materials

   OECD 406, Organization for Economic Co-Operation and Development (OECD), Guidelines for the Testing of Chemicals, “Skin Sensitization”, adopted 17 July, 1992, corrected 14 June 2021.

   ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 08/24/2023

Labcorp Bedford, LLC **Fiscal Year 2022**

Annual Report of Research Facility
Column E Explanation Form

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1. **Registration Number:** 14-R-0101

2. **Research Facility Headquarters address:** 15 Wiggins Ave Bedford, MA 01730

3. **Number of animals used in the study:** 2

4. **Specie (common name) of animals used in this study(s).** Rabbit

5. **Explain the procedure producing pain and/or distress.** (b) (4) [redacted]

6. **Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results.**

   (b) (4) [redacted]

7. **What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g. APHIS, 9 CFR 113.102):**

   FDA 21 CFR Part 610.13(b) *Test for pyrogenic substances.*

   FDA, CDRH, June 16, 2016, Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluations and testing within a risk management process”

   ISO 10993-11, 2017, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.

   ISO 10993-12, 2021. Biological Evaluation of Medical Devices – Part 12: Sample Preparation Reference Materials

   USP-National Formulary 2021. <151> Pyrogen Test & USP-National Formulary 2022. <151> Pyrogen Test

   ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.

Obtained by Rise for Animals.
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