1. CERTIFICATE OF CONFORMITY

2. Standards: **Code of Federal Regulations Title 21**

3. Equipment Description: **400ND White Silicone Pharmadrum O Ring – 40 Shore**
3.1 *Pharmatech* Part Reference: **F000802**
3.2 Batch Number: **12898/12549**

4. Manufacturer: *Pharmatech*, **6 Forge Mills Park, Station Road Industrial Estate, Coleshill, Warwickshire. B46 1JH. U.K.**

5. This equipment and any acceptable variation thereto are specified in the **Technical Specification Datasheet**. This equipment is intended for use as a Gasket between Lid and Vessel Body of a corresponding diameter Pharmatech Vessel.

6. *Pharmatech certifies that the goods supplied against the above purchase order have been designed and manufactured from **Platinum Cured Silicone Rubber (NGP40)** in line with the Technical Specification in a production process managed by a certified ISO 9001 Quality Assurance System. It has been inspected and is certified free from any imperfections.*

7. Standards of manufacture are, but not limited to, the following:

7.1 **FDA CFR Title 21 Schedule 177.2600 -** *Rubber articles intended for repeated use.*

7.2 Free from animal derived products or raw materials in line with EU Guidance **EMA/410/01.**

8. *It is the responsibility of the customer to ensure that this equipment is thoroughly cleaned before first use by their own internal validated cleaning process for Silicone products.*

9. This certificate relates only to the design and construction of the Equipment listed above and applies only for the intended use as specified in paragraph 5.

Shaun O'Riordan
QA & Document Manager
Date: 23 Jan 2019