


1. CERTIFICATE OF CONFORMITY

2. Standards: **Code of Federal Regulations Title 21**
3. Equipment Description: **305ND White Silicone Pharmadrum O Ring – 40 Shore**
- 3.1 *Pharmatech* Part Reference: **F000801**
- 3.2 Batch Number: **12898/12548**
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.

This is to certify that the equipment described herein ("Certified Equipment") has been manufactured to the specification identified above, in accordance with the standards and definitions dictated within *Pharmatech's* Quality Assurance Manual. This certificate and test results obtained apply only to the certified equipment as submitted by *Pharmatech*.

The certificate may not be used, in whole or in part, in any other document without *Pharmatech's* prior written approval.


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

