

Declaration of Conformity

We,

Spiracle Technology

10601 Calle Lee, #190

Los Alamitos, CA 90720 U.S.A.

Tel: (714) 418-1091 Fax: (714) 418-1095

Declare that the product(s) listed below:

| | | |
|-------------------|---|--------------------------|
| | MVP (Manual Vacuum Pump) | |
| Product | FERNO2, MVP (Manual Vacuum Pump) | |
| Model | T60540 | |
| Type/Group | Refer to Below Codes Listing | |
| Item No. | Name | Codes Listing No. |
| 1 | Spiracle Technology, FERNO2, MVP (Manual Vacuum Pump) | T60540 |

which this declaration relates, is in conformity with the following standards or other normative documents :

STANDARD/REQUIREMENTS

EN ISO 13485:2016

EN ISO 14971:2019

EN ISO 10651:2009

EN ISO 5356-1:2004

EN ISO 10079-2:2009

EN ISO 10993-1:2018

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN980:2008

EN1041:2008+A1:2013

CE MDD: Cert. by mfg.

2007/47/EC

ASTM F920-93

FDA Establishment 2030745

FDA 510(k) Class 1 - Not Applicable (exemption)

CE Class 1, Rule 1, Annex VIII, Regulation (EU) 2017/745

Issued by,

Spiracle Technology

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Los Alamitos, CA 90720 U.S.A.

Date: 10-19-2020



Michael Sarné

Managing Director