Pelican Feminine Healthcare Limited, trading as Single Use Surgical and Pelispec (PFHL)

EU MDR & Brexit Statement

04th June, 2019

Background: The MDR is a significant development and strengthening of the existing regulatory system for medical devices in Europe and will replace the original directives which have been in place for over 25 years.

The European Union's Medical Device Regulations 2017/745, or MDR, becomes fully effective for new products, or significant changes to existing products, to be placed on the EU Market from May 2020. The MDR replaces the existing Medical Device Directive, or MDD.

The legislation now being in the form of a Regulation, rather than a Directive, means that the EU law is directly enforceable as in all member states without requiring transposition by each member state into national law. This will allow for greater legal certainty and prevents variation in the approach taken or in the rules relating to medical devices that are applied across EU Member States.

PFHL & SUS position:

We will continue to develop and produce medical device products that are safe, reliable and effective. The MDR is a welcome improvement in the EU regulatory system for medical devices. It will allow for an effective, consistent and robust regulatory framework for medical devices across Europe. Above all this regulation puts patient safety first.

We have taken the following steps to ensure we can continue to legally supply, our existing MDD EC certified product portfolio to our customers after May 26th, 2020. We have requested extension of existing MDD EC certificates with our Notified Body, which will allow us to continue to place existing products, that are currently MDD EC certified, on the EU Market up until May 26th, 2024. In the interim period, we will be phasing in MDR compliance across applicable product lines. To help assist our customers in understanding whether product is conforming to the MDD or the MDR from May 2020, our EU Declaration of Conformity document will show both MDD and MDR compliance status, as appropriate, to each model series.

All new products brought to the EU market after May 2020, or significant changes to existing devices on or after this date, will fully comply with the MDR. Under the provisions outlined above, PFHL will continue to supply Medical Devices with MDD Certificates after May 2020.

PFHL management will continue to ensure we are in a state of MDR audit readiness.

Brexit position:

With the uncertainty around Brexit, we have instigated contact with the EU arm of our Notified Body and have an agreement in principle in place with an EU representative, to reduce the impact on our customers. We have been assured that the Notified Body transfer process is very short and can be enacted at any time.

As soon as we know whether the UK is leaving the EU with our without a "deal", we will take the appropriate action to ensure continuity of regulatory compliance.

This statement will be updated as new information becomes available.