



Date: 29-Feb-2020

To: **Whom it may concern,**

Subject: **Change of EU Notified Body**

We, Pleasure Latex Products Sdn. Bhd. hereby inform you, that we have change our EU Notified Body from SGS UK to MEDCERT Germany which effective from 25.02.2020 (refer attached certificates). Thus, this invalidate the previous SGS ISO 13485 & CE certificates.

We have signed "Transfer Agreement" with MedCert (Germany) and SGS UK and which SGS Belgium allows Pleasure Latex Product Sdn. Bhd. to continue shipping the CE 0120 marking medical devices for up to 6 months, i.e. to 20 August 2020. This is to use up the pre-printed packaging materials. Refer below statement that extracted from agreement:

4. In terms of labelling requirements (as per NBOG BPG 2006-1), the following shall be specified:
  - a) From 20<sup>th</sup> August 2020, **Manufacturer** will no longer use the identification number of **SGS** in any labelling of devices which are produced. This represents a 6 months transition period for labelling, this being commensurate with the different industrial manufacturing processes of products and associated artefacts which will require change.
  - b) The same applies to the utilization of **SGS** identification number and logo in brochures, advertising materials and other documents. Likewise, the identification number of **SGS** in manuals will not be used after 20<sup>th</sup> August 2020.
  - c) Change of label of the Notified Body shall be specified for a certain product or charge number and documented within the scope of product records.
  - d) Products manufactured during the transition period 20<sup>th</sup> February 2020 (transfer date) to 20<sup>th</sup> August 2020 (transfer date plus 6 months) can continue to be placed on the market with the identification number of **SGS**.

As for our customer (business partner), once you received the CE 0120 marking shipment, the medical device can continue to be placed on the market until the medical device expiry date as printed on the packaging.

The time limit to ship the CE 0120 marked medical devices is on Pleasure Latex Products Sdn. Bhd. only.

Yours Sincerely,

Ms Irene Ting,

QA Manager

