EC DECLARATION OF CONFORMITY

EXCILOR KLOVEN BEHANDELING VOOR HANDEN & VOETEN

EC declaration of conformity for the medical device named
"EXCILOR KLOVEN BEHANDELING VOOR HANDEN & VOETEN
"

manufacturer PASQUALI s.r.l., CE marking no. 16014/I, issued by Certiquality s.r.l. (0546), Via G. Giardino 4-20123 Milan, on 29/12/2011 according to Annex V of Directive 93/42/EEC as amended by Directive 2007/47/EEC

The undersigned company ***PASQUALI s.r.l.***, Viale Belfiore 41 – 50144 Firenze (FI), which is the manufacturer of the medical device named

"EXCILOR KLOVEN BEHANDELING VOOR HANDEN & VOETEN
"

manufacturing batch no.: R0340B1E **quantity:** 9.942

preparation of: 21.02.2020 **expiry date: 2024/02**

DECLARES

that the batch complies with all applicable provisions laid down in Directive 93/42/EEC as amended by Directive 2007/47/EC on medical devices.
To this end, the undersigned company guarantees, under its own responsibility, the following:

- the said batch meets the essential requirements laid down in Directive 93/42/EEC as amended by Directive 2007/47/EC;
- the said batch is a device belonging to CLASS IIa according to the classification rules set out in Annex IX, Section 1.4, Rule 4 of the Directive;
- the device is manufactured according to the technical documentation provided for by Annex VII of Directive 93/42/EEC, which is kept by the Technical Director of Pasquali s.r.l.;
- the said batch is marketed in NON-STERILE packaging;
- the said batch IS NOT A MEASURING INSTRUMENT;
- the said batch was submitted to risk assessment according to the UNI EN ISO 14971:2012 standard;
- the said batch IS NOT INTENDED FOR CLINICAL INVESTIGATIONS;
- the manufacturer set up a regular procedure for assessing the experience gained from post-manufacturing use of medical devices as well as for designing an appropriate system to apply corrective actions, as

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necessary, in case of accidents or near accidents according to the provisions laid down in Annex V, Section 3 of the Directive;

- the manufacturer undertakes to keep and make the technical documentation available to competent Authorities for at least five years after the last manufacturing date of the product.

This declaration of conformity for the medical device named "EXCILOR KLOVEN BEHANDELING VOOR HANDEN & VOETEN" relative to the said batch is issued under the responsibility of the manufacturer Pasquali s.r.l.

Date:
13.02.2020

Seal and signature
(Sole Director)