ISO 13485

TRICOMED S.A.
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Łódź, 4/05/2020

To whom it may concern,

In connection with the application from 26 May 2020 of the Regulation of the European Parliament and of the Council of the EU 2017/745 of 5 April 2017 on medical devices (the MDR Regulation)

TRICOMED SA

declares that:

we are a manufacturer and distributor of medical devices from classes I to III (included), therefore, the requirements provided for in the Regulation will be successively introduced until 2025 - in accordance with the relevant deadlines and transition periods determined in the Regulation.

Medical devices under the TRICOMED SA brand, classes IIa, IIb and III, subject to certification with the participation of a Notified Body - all have CE certificates, valid until 2022, 2023 and 2024, confirming the compliance of devices with the Directive 93/42/EEC (MDD Directive).

In accordance with art. 120 p. 2 of the Regulation, certificates issued by Notified Bodies in accordance with Directive 93/42/EEC from May 25, 2017 remain valid until the end of the period indicated in the above-mentioned documents. Thus, the products that were lawfully marketed on the basis of Directive 93/42/EEC before May 26, 2020 and products that were marketed after May 26, 2020 on the basis of these certificates, may be made available on the market or put into service until the date of validity of the mentioned documents expires, together with declarations of conformity validating the compliance of these products with the requirements of Directive 93/42/EEC. After this date, further certification of Class IIa, IIb and

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III products will be continued and the relevant certificates will be made available by TRICOMED SA.

Class I non-sterile medical devices (Codofix, Codofix Plus, Codoban, and Codosil Adhesive), whose compliance is assessed by the manufacturer independently, will be placed on the market from May 26, 2020 on the basis of new declarations of conformity validating compliance with the requirements of the Regulation 2017/745.

In addition, we would like to inform that:

- The MDR Regulation in Annex VIII introduces changes to the current classification of medical devices under the TRICOMED brand. Thus, the classification of mesh products on our offer (Optomesh, Optomesh Ultralight, Dallop NM, Dallop NM Ultralight, G-Mesh) will change to a higher class. Moreover, reusable surgical instruments (Applicators), in accordance with with the MDR Regulation art. 52, will require the participation of a Notified Body in the conformity assessment procedure.
- The conditions for storage and transport of medical devices have not changed and are specified in the quality management system documents. The storage and transport conditions are also included on product labels.
- TRICOMED SA has a certified quality management system, compliant with the requirements of PN-EN ISO 13485:2016, certificate no. M-76-a / 1/2019 (issued by PCBC SA).

TRICOMED S.A.
PREZES ZARZĄDU
dr hab. inż. Witold Sujka