



MEDISEPT
Perfect disinfection

Lublin, 20th February 2023

Information on the legal status of Medical Devices offered by MEDISEPT

Dear Sir or Madam,

As manufacturer of medical devices MEDISEPT company offers products under Directive 93/42/EEC till 16th February 2023.

As a manufacturer we have fulfilled all necessary requirements for certification in accordance with new legal requirements: Regulation 2017/745 (amending the existing rules for conducting audits and issuing certificates for medical devices).

President of URPLW MiPB – Polish Competent Authority – made a decision on 20th February 2023 based on Article 94 of MDR Regulation that our medical devices do not presenting an unacceptable risk or other non-compliance.

According to Article 97 of MDR there was made decision products can be sell till 16th February 2024.

MEDISEPT company meets all requirements for decision:

1. At the day of submitting an application to Polish CA MEDISEPT company has had valid certificates for EN 13485 and 93/42/EEC till 16th February 2023.
2. MEDISEPT company has had confirmation of date of the first certification phase and has had signed contract for certification. We want to inform we are after first phase of certification which has placed on 15th February 2023 according to new legal requirements.
3. All medical devices produced by MEDISEPT company are made according to QMS adapted to new legal requirements. QMS was prepared according to requirements mentioned in MDR Regulation, including Article 120 and 83 of MDR Regulation.
4. As a manufacturer we declare we will not make and did not make changes in ingredients or filed of use in our products and did not make significant changes in products' presentations.
5. Application concerns only products listed on MDD certificate and transfer to MDR application. For mentioned products the certificate issued in accordance with the 93/42/EEC has not been suspended or withdrawn by notified body.
6. Based on notified body declaration the issue of certificate could take 1 month to 6 months.

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MEDISEPT Sp. z o. o., Lublin, 20-270, ul. Ludwika Spiessa 4, Poland, the National Court Register under KRS no. 0000020407 by the District Court Lublin-Wschód in Lublin, with its registered in Świdnik, 6th Commercial Division of the National Court Register, VAT No. PL 946-001-00-16, Business Identification Number (REGON) 430566102. Share capital 622,000,00 PLN | Office: MEDISEPT Sp. z o. o. ul. Ludwika Spiessa 4, 20-270 Lublin | Warehouse: ul. Ludwika Spiessa 4. 20-270 Lublin | Contact: phone.: +48 81 535 22 20.



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7. As a manufacturer we declare that we will deliver certificate immediately upon receipt to the Polish Competent Authority – URPLW MiPB.

Because of new regulations requirements, both in Poland and throughout the European Union, there were long delays in the certification process of medical devices, which were results of:

- a) Notified bodies had to prepare themselves for the process of certification of entities in accordance with the new regulation and today only limited number of notified bodies (out of all that have been certifying medical devices) is ready to conduct an audit in accordance with the new regulations;
- b) The number of applications for certification of medical devices submitted by manufacturers has increased dramatically because of need of extending certificates according to new regulation;
- c) The audit process itself is longer than the one according to existing requirements (93/42/EEC).

At the same time, we would like to inform you that this is a situation concerning the entire European market. In order to mitigate the effects of the long certification period and thus the high risk of lack of medical devices on the European market, the European Commission voted to amend Regulation 2017/745.

The vote took place on 16th February 2023 and according to new requirements Regulation will extend the transitional periods for medical devices until 31st December 2027. The amendment will enter into force on the day of its publication.

Yours sincerely

V-ce President

Waldemar Ferschke

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