

EC Certificate



Production Quality Assurance MDD Annex V

Registration No.: DD 1497675-1

Manufacturer: Instytut Biotechnologii Surowic
i Szczepionek BIOMED Spółka Akcyjna
(IBSS BIOMED S.A.)
Al. Sosnowa 8
30-224 Kraków
Poland

Products: - Vaginal pessaries, non-sterile

Replaces EC Certificate, Registration No.: DD 60117500 0001

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.