

EC Certificate

**Production Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex V**



Registration No.: DD 1498070-1

Manufacturer: Promet-Plast s.c.
Godzikowice 50a
55-200 Oława
Poland

Products: For the following devices, the scope only covers the aspects of manufacture concerned with the conformity of the products with metrological requirements:

- Medicine dispensing cups

Replaces EC Certificate, Registration No.: DD 60127986 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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A blue ink signature is written over a circular seal. The seal contains the TÜVRheinland logo and the text 'TÜV Rheinland LGA Products GmbH' and 'Zertifizierungsgesellschaft'. Below the signature, the name 'Daniel Świątko' and the company details 'TÜV Rheinland LGA Products GmbH, Tillystraße 2 · 90431 Nürnberg · Germany' are printed.

Daniel Świątko
TÜV Rheinland LGA Products GmbH
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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.