

## APPROVAL

EC Directive 93/42/EEC Annex V, Article 3  
Quality Assurance System Production

Registration No.: DD 60040641 0001

Report No.: 26300113 002

**Manufacturer:** Unidem Ltd Spółka Komandytowa  
ul. Towarowa 23a  
43-100 Tychy  
Poland

**Scope:** Manufacture of disposable medical devices  
(see attachment for products included)

**Date of Expiry:** 19.09.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex V, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex V, Article 4 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Date 20.09.2011

Notified Body

*Breder*  
Dr. J. Breder



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and  
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** DD 60040641 0001  
**Report No.:** 26300113 004

**Manufacturer:** Unidem Ltd Spółka Komandytowa  
ul. Towarowa 23a  
43-100 Tychy  
Poland

**Products included:**

- Sterile hypodermic needles for single use
- Sterile infusion sets for single use
- Sterile dental injection needles for single use

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Sterile vaginal speculums for single use
- Sterile urine drainage bags for single use
- Sterile gynecological kits for single use
- Sterile cervical rambrushes for single use
- Sterile cell brushes for single use
- Sterile otolaryngological sets for single use
- Sterile nasal speculums for single use

**Date:** 2012-10-18

**Notified Body**

*Breder*  
**Dr. J. Breder**

