

MINIPLAST EIN-SHEMER
Agricultural Cooperative Society Ltd.
KIBBUTZ EIN-SHEMER
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מיניפלאסט עין-שמר אגש"ה בע"מ
קובוץ עין שמר ד.נ. חפ"ד מיקוד 37845
טל 04-6374395-435
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מס'ת 57038604
E-mail: miniplast@ein-shemer.org.il

EC DECLARATION OF CONFORMITY

according to annex III of the Council Directive 98/79/EEC concerning in vitro diagnostic medical devices

We: MINIPLAST EIN-SHEMER, Agricultural Cooperative Society Ltd, Kibbutz, Ein-Shemer, Post Hefer 37845, Israel

(PHONE: 972-4-6374395; FAX: 972-4-6371919)

declare under our sole responsibility that the product:

**Urine Cup 120 ml,
Test Tubes 15ml and 50 ml
Petri Dishes 90 mm**

meet the provisions of the Council Directive 98/79/EEC concerning in vitro diagnostic medical devices which apply to them:

The products are intended to be used for collection of body fluid and tissue samples as a "specimen receptacle", therefore are not covered by Annex II of the IV Diagnostic Medical Device Directive.

Conformity assessment was performed according to Annex III of the Directive.

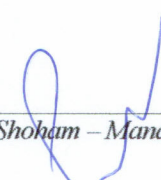
The following standards were used to prove the products' conformity with the essential requirements of the above Directive:

- EN ISO 9001:2000 – Quality Systems-Model for quality assurance in design, development, production, installation and servicing;
- ISO13485:2003 – Quality Systems-Medical Devices-System requirements for regulatory purposes
- EN ISO 10993-1:2003 – Biological evaluation of medical devices-Part 1: Evaluation and testing;
- EN 980:2003 – Graphical symbols for use in the labeling of medical devices;
- EN 1041:1998 – Information supplied by the manufacturer with medical devices;
- EN 14971:2000 – Medical devices-Application of risk management to medical devices
- EN 13612:2002 - Performance evaluation of in vitro diagnostic medical devices

The authorized representative within the EU who has been empowered to enter into commitments on our behalf:

MedNet GmbH, Borkstrasse 10, D-48163 Muenster, Germany; Tel. 49-2513-2266-0; Fax: 49-2513-2266-22
(Name, address, phone and fax numbers)

Date:


Omri Shoham – Managing Director
