144494-14-06-10

EC DESIGN-EXAMINATION CERTIFICATE

Directive 93/42/EEC on Medical devices, Annex II (4)

CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

Panaxia Ltd.

Headquarters: **1 Bat sheva St., Lod, Israel**

Authorised representative: **MedNet GmbH, Borkstrasse 10, 48163 Muenster, Germany**

Scope:

Calcium hydroxyapatite dermal fillers

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
calcium hydroxyapatite dermal implant	Crystalys	sub-dermal and deep dermal use	Crystalys Crystalys Gentle	III
calcium hydroxyapatite dermal implant	Hydroxytite	sub-dermal and deep dermal use	Hydroxytite Hydroxytite Gentle	III

This certificate is valid only with the system certificate No. **144493-14-06-10**, in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 79-GY-140320

Issue: 1
Issued: 10 June 2014
First issued: 10 June 2014
Start date of certified status: 10 June 2014

Expires:
09 June 2019

CE Certiso
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