



Declaration of conformity

**Manufacturer : SOLEKO S.p.A VIA Ravano S.n.C
03037 Pontecorvo (FR) Italy**

Product: Polyvue Standard – Polyvue Custom – PV3- SL Three color – SL1 Color – Queen Color Toric – SL 38 Color toric – SL 38 Toric – ST3 Toric – T1 – Twins – Solitaire Toric – Trilogy

Soft contact lenses, with 43% water content. GMDN 36055 - A device that is a corrective ophthalmic contact lens that is applied directly to the front surface of the eye. This device is reusable.

Classification: II a - rule 5.2

Conformity assessment Route:

We hereby declare that the above mentioned product meets the provisions of Essential Requirements, the Council Directive 93/42/EEC annex II section 3 and the subsequent Council Directive 2007/47/EEC concerning Medical Devices. All supporting documentation is retained under the premises of the manufacturer. The product is manufactured in accordance to the ISO and specifications detailed within the technical file and the relevant medical device for Contact Lenses.

The Quality Management System is certified under EN ISO 13485:2012

Soleko S.p.A. is a registered CE brand and acts in compliance annex II section 3 of Directive 93/42/EEC and the subsequent Council Directive 2007/47/EEC concerning Medical Devices.

CE 0123

Notified Body:

**TÜV SÜD PRODUCT SERVICE GmbH
Ridlerstrasse 65 D-80339 München Germany**

(EC) Certificate:

N° G1 14 10 26633 017

Date of expiry:

20/11/2016

Date and Signature: 03/11/2014


Guido CARNACINA
Legal representative