EVPÚ®

NOTIFIED BODY No. 1293

EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical devices, as amended by 2007/47/EC of the EP and of the Council of 5th September 2007, Annex II (with the exemption of section 4), transposed into "Slovak government decree No. 582/2008 Coll. of Laws" as amended

No. 40041/101/1/2011/CE

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC, as amended by 2007/47/EC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Manufacturer and Facility	**DUEBA Contact Lens** **3F Beommul APT Type Factory 1287-1 Beommul-dong** **Suseong-Gu, Daegu, Korea**
Product(s)	**Soft contact lens**
Product type(s)	**Messish, The zone, Cool day, Barbie, Any C,** **C more, Alamode, Belita, Clara, Luxa, Namy**
Classification of medical device	**Medical Devices – Class IIa**
Scope of quality system	**Quality of design, production, storage and distribution of Soft contact lens**
Final report number	**40041/2011/C**
Date of issue	**March 23rd, 2011**
Date of the end of validity	**March 22nd, 2016**

EVPÚ, a.s. NOVÁ DUBNICA Notified Body No. 1293

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The CE 1293 Marking may only be used if all relevant and effective Directives of EP and Council are complied with.

The Notified Body has audited the quality system in accordance with the Directive 93/42/EEC, as amended by 2007/47/EC Annex II (3) and found that the quality system meet the requirements of the Directive 93/42/EEC, as amended by 2007/47/EC Annex II.

The manufacturer must inform EVPÚ a.s. of any plan for substantial changes in the design, construction of the products or the quality system of production in order to examine whether this Certificate remains valid. Annual Surveillance Audits will be held to verify the validity of this Certificate.

This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments to the Directive 93/42/EEC, as amended by 2007/47/EC may render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with the Directive 85/374/EEC.

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