





EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-084

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 on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

GBL GÜL BİYOLOJİ LABORATUVARI SANAYİ VE TİCARET LİMİTED ŞİRKETİ

DUDULLU OSB. MAH. İMES-305.SK C BLOK NO:16 ÜMRANİYE, İSTANBUL, TURKEY

Product: Medical Device Disinfectants

The products defined at the enclosure which is the part of this certificate and contains one page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number:

M.3347.10

Date of first issue:

01 March 2011

Date of last issue:

08 January 2020

Revision Number:

06

Expiry Date:

13 February 2024

08 January 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel Head of Notified Body







Enclosure of the EC Certificate:

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Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-11-084, Revision Number: 06

Concerned medical devices;

Product: Invasive and Non-Invasive Medical Device Disinfectant

Types	Model Number
GBL® SURFACTO™ DIAPP	6001
GBL®SANITAROSA™ GA	6071
GBL®SANITAROSA™ OPA	6026
GBL®PEROXY PLUS RP	6127
GBL®CITRO™ PLUS	6106
GBL®PEROXY™ PLUS	6123
GBL®CITRO™ BRA	6102
GBL®CITRO™ GAM	6105
GBL®PEROXY™ HLD	6128
GBL®SANITAROSA™ GA ACT	6002
GBL®CITROTAL 100™	6338
GBL®PEROXY™ PLUS LIGHT	6126

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

08 January 2020, Istanbul, Turkey

Muhteşem Gökhan Yücel Head of Notified Body