# CERTIFICATE

**kiwa**

## EC Certificate

## Full Quality Assurance System according to

## Medical Devices Directive 93/42/EEC Annex-II Section 3

### Certificate Number: 1984-MDD-14-262

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:**

## KUZEY SAĞLIK ÜRÜNLERİ
## VE KİMYA SANAYİ ANONİM ŞİRKETİ

İstanbul Yolu Ergazi Mah. Gersan San. Sitesi 2310 Sok. No:47
Yenimahalle, Ankara, Turkey

**Products:** Invasive and Non-Invasive Medical Device Disinfectant

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.4172.04 |
| **Date of first issue:** | 15 January 2014 |
| **Date of last issue:** | 11 January 2018 |
| **Revision Number:** | 02 |
| **Expiry Date:** | 27 December 2019 |

11 January 2018, Istanbul, Turkey

Head of Notified Body
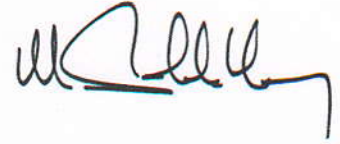
**Enclosure of the EC Certificate:**

**Full Quality Assurance System according to**

**Medical Devices Directive 93/42/EEC Annex-II Section 3**

**Certificate Number: 1984-MDD-14-262, Revision 02**

Concerned medical devices;

| Product Name | Models |
|---|---|
| Non-Invasive Medical Device Disinfectant | Trisalva, Trisalva Spray, Alvatech Spray, Ecodent, Biguanide Spray |
| Invasive Medical Device Disinfectant | Vigasepton, Sencron 1, Sencron 2, Sencron 2r, Clinosure, Clinosure 2, Clinosure 20, Enzycare, Oxforte, Peracitt, Rivasol (Solution), Dicideral Touch (Solution), Oprezan, Lystamin, Opacitt |

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

11 January 2018, Istanbul, Turkey          Head of Notified Body

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