**Declaration of Conformity (DoC) Corrigendum**

**Manufacturer's Declaration**

To whom it may concern,

This corrigendum intends to correct the following information in DoC of the listed products.

| **Product Identification** | | | |
|---|---|---|---|
| **Product Name** | **Class** | **Part Number/ Catalogue Number** | **Basic UDI-DI** |
| RenalGuard Single Use Set | IIa, Rule 2 | AC00050 | (01)00866379000108 |
| RenalGuard Console | IIb, Rule 11 | FM1 | (01)008663790012 2 |
| **EMDN Code:** A03010105, A99 | | | |
| **Intended purpose:** | | | |
| The RenalGuard System is indicated for temporary (up to 14 days) replacement of urine output by infusion of a matched volume of sterile replacement solution to maintain a patient's intravascular fluid volume.<br>The RenalGuard System is not intended for the infusion of blood, blood components, medications, or nutritional fluids.<br>All treatments administered via the RenalGuard System must be prescribed by a physician.<br>The RenalGuard System is intended to be used in a monitored hospital environment, such as an interventional lab or an intensive care unit, by medical personnel instructed in the use of the device. | | | |
| **Products Components** | | | |
| RenalGuard Console | | FM1 | |
| RenalGuard Single Use Set | | AC00050 | |
| RenalGuard Cart | | WH00012 | |
| **MDD CE Certificate reference** | | | |
| 44 232 117839<br>Original Expiry Date: 31 July 2023 | | | |
| **Notified Body name and number that issued the Directive Certificate** | | | |
| TUV NORD CERT GmbH 0044 | | | |
| **Notified Body name and number where the MDR application was lodged/contract signed** | | | |
| TUV NORD CERT GmbH 0044 | | | |
| **Date of the Declaration of Conformity (DoC)** | | | |
| 28-May-2019 | | | |

Digitally signed by Botnaru Andrei
Date: 2024.05.27 09:27:11 EEST
Reason: MoldSign Signature
Location: Moldova

The amendment allows previously issued MDD certificates which are expired, to be recognized as valid under certain specified conditions.

This Declaration is issued under the sole responsibility of CardioRenal Systems Inc, to support the applicability of MDR (EU 2017/745) Article 120 via (EU) 2023/607, amending MDR as regards to the transitional provisions for its legacy devices for which the MDD certificate expired before the issuance of a MDR certificate.

According to regulation (EU) 2017/745, for legacy devices according to Article 120(3), no changes to DoC signed prior to May 26, 2021 can be performed. Therefore, the existing DoC is still valid and this Corrigendum, will be attached

to the originally signed DoC. The DoC will be updated upon transition to MDR.

We declare that:

- The certificate referred to the above was issued by TUV NORD CERT GmbH 0444 under the requirements of the Medical Device Directive (93/42/EEC)
- The certificate referred to above was issued prior to 26 May 2021
- The certificate referred to covers the legacy devices specified above.
- The certificate referred to above has expired on 31 July 2023 (and was valid at the date of its expiry, neither have suspended nor withdrawn) The device continues to comply with Directive 93/42/EEC
- There are no significant changes in the design and intended purpose
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.
- The Company's QMS complied with the MDR Article 10 (9) requirements related to PMS, vigilance, market surveillance and registration of actors and devices.

The extension of the transitional period and concomitant extension of the certificate's validity is done automatically by law, provided conditions laid down in Article 120 (3c) MDR are fulfilled. Therefore, the devices covered by MDD certificate CE number 44 232 117839 and MDD Declaration of Conformity may be placed on the Market or put into service until **31 December 2028.**

Company Representative Name: Shmulik Adler
Title: SVP RA and Clinical Affairs Signature:
Place: Milford, MA, USA Date: 6th February 2024

| | |
|---|---|
| **Manufacturer name** | CardioRenal Systems Inc. |
| **Manufacturer address & contact details** | 459 Fortune Blvd<br>Milford, MA 01757 USA<br>sadler@renalguard.com<br>Direct Tel: + 972-52-6894949<br>Office: +1-508-520-2550 |
| **Single Registration Number (SRN)** | US-MF-000035063 |

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|---|---|
| **Authorised Representative name** | Dieter Hupens |
| **Authorised Representative address & contact details** | PLC Systemas Medicos Intern. (Deutschland) GmbH<br>Borsteller Chaussee 55 \| 22453 Hamburg \| Germany<br>Mobile: +49 175 240 3210<br>dhupens@renalguard.com |
| **Single Registration Number (SRN)** | DE-AR-000020280 |

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|---|---|
| **Notified Body name** | TUV NORD CERT GmbH |
| **Notified body number** | 0044 |