

To whom it may concern

Date: 2025-04-07

Statement on the continued validity of EC Certificate No. 10000379653-PA-NA-DNK under Regulation (EU) 2023/607

KEN Hygiene Systems A/S confirms that EC Certificate No. 10000379653-PA-NA-DNK Rev. 0.0, issued under the Medical Device Directive 93/42/EEC (MDD) by DNV Product Assurance AS (Notified Body No. 2460), remains valid despite the formal expiry date of 1 March 2024.

This continued validity is based on the transitional provisions introduced by Regulation (EU) 2023/607, which amends Regulation (EU) 2017/745 (MDR). In accordance with Article 120(3c) of the MDR, as amended, MDD certificates may remain valid during the extended transition period provided that the following conditions are fulfilled:

1. A formal MDR application has been submitted to a Notified Body by 26 May 2024.
2. A written agreement has been signed between the manufacturer and the Notified Body by 26 September 2024.
3. The Notified Body continues to carry out appropriate surveillance under the MDD.

KEN Hygiene Systems A/S has fulfilled these requirements, as confirmed in the following supporting documentation:

- Notified Body Confirmation Letter from DNV, dated 27 February 2024, confirming receipt of the formal MDR application, a signed written agreement, and DNV's continued surveillance of the MDD-certified devices.
- Addendum to the Product Certification Agreement, signed by both parties, confirming coverage of the relevant devices under MDR transitional provisions and ongoing surveillance audits in accordance with Article 120 of MDR.
- EC Certificate and product list, showing that the certificate in question covers the devices now included in the MDR application.

Accordingly, the EC certificate remains valid under EU law and continues to provide evidence of conformity for the listed devices during the transitional period, at the latest until 31 December 2028, subject to continued compliance with MDR Article 120(3c).

Sincerely,


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