

ADDENDUM

Customer	Name: KEN Hygiene Systems A/S	Official/Org Id#: NA VAT/Tax#: D.K-10676096
	Address: Bøgebjergvej 60, 5672 Broby, Denmark SRN#: DK-MF-000017727	
	Contact Person: Freddie Rasmussen	Tel: +45 62 63 10 91 E-mail: ken@ken.dk
DNV	Legal Entity: DNV Business Assurance Denmark A/S	Address: Tuborg Parkvej 8 DK-2900 Hellerup Denmark
	Contact person: Martin Lindvall	Tel: E-mail: Martin.Lindvall@dnv.com
Notified Body /Auditing organization/Certification body	Legal Entity: DNV Product Assurance AS	Notified Body nr: 2460
Work/Project Agreement no:	PRJN-498060	

This Agreement shall consist of: The Product Certification Agreement already entered into between the parties and this Addendum, which together constitute the integrated entire Agreement between the Parties. The above listed documents in the Agreement shall be interpreted as one agreement and in case of any ambiguities or contradictions between the various documents, the documents shall take precedence in the order listed here: The Addendum, The Product Certification Agreement. Any terms and conditions included in purchase orders, standard terms or similar from the Customer shall be disregarded and not affect the terms of this Agreement, even if signed by Parties. Any such Customer's purchase orders shall be deemed relevant for invoicing purposes only. This Agreement may only be amended in writing between the Parties. Should any provision of this Agreement be held to be invalid or unenforceable, such shall not affect the validity or enforceability of any other part or provision of this Agreement. Such provision shall be amended to the extent necessary to make the provision valid and enforceable, while keeping as strictly and closely as possible to the original wording and purpose of the provision. This Agreement is made in three copies, one original for each Party hereto.

Expanded Scope: Products certified under Directive 93/42/EEC to be covered in surveillance audits in accordance with article 120 of MDR


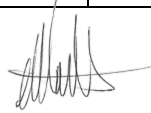
Product name/ Basic UDI-DI (under MDR application)	MDR Classification	Corresponding device in MDR application	MDD Certificate (s) number covering the devices under MDR application	Deadline for submission of complete and up to date Technical Files to DNV
IQ (Washer-Disinfector) Basic UDI-DI: 5713437KENIQWV	IIb	Product Description: IQ (Washer-Disinfector) IQ3/MAT LD100BM IQ4/MAT LD100 IQ5/MAT LD500 IQ5-M/Mat LD500M IQ6/MAT LD1000 IQ10	Certificate number: 10000379653-PA-NA-DNK Rev. 0.0 Expiry date: 2024-03-01	
BWD (Bedpan Washer) Basic UDI-DI: 5713437KENBWDUU	IIa	Product Description: BWD (Bedpan Washer) BWD 731/MAT LC10 BWD 733/MAT LC20 BWD 736/MAT LC30 BWD 738	Certificate number: 10000379653-PA-NA-DNK Rev. 0.0 Expiry date: 2024-03-01	

Special conditions

For the provision of services as set out in Expanded Scope, the following special conditions shall apply:

Any work related to devices listed in the Expanded Scope shall be subject to the Customer submitting up-to-date and complete technical documentation as specified by DNV within deadline(s) set out in the Expanded Scope (“the Deadline”). Customer acknowledges and agrees that DNV’s performance of the Work set out in the Expanded Scope requires DNV to be granted access to all relevant information required within the Deadline. If the Customer fails to meet the Deadline, DNV shall be entitled to terminate the Agreement with immediate effect with regard to all work related to the Expanded Scope. DNV shall be entitled to full remuneration for the Work carried out prior to the termination and for all documented incurred unrecoverable costs. The Customer shall indemnify DNV Group from any claims arising out the Customer’s breach of the obligations set out in this clause. The Customer shall indemnify DNV Group from any claims arising out the Customer’s breach of the obligations set out in this clause.



On behalf of Customer		DNV Market Unit		DNV Product Assurance AS	
Place: Broby	Date: 2024-02-23	Place: Hellerup	Date: 2024-02-26	Place: Oslo	Date: 2024.02.24
Signature  Name: Freddie Rasmussen Function: Quality Manager		Signature  Name: Martin Lindvall Function: Operation Manager		Signature Name: Björg Synnøve Nesgård Function: Head of Certification Processes	
<i>The undersigned hereby declares:</i> <ul style="list-style-type: none"> • <i>that the information given in this document is correct, and that the same application has not been lodged with any other Notified Body</i> • <i>The declarations and data in the Quotation Request form remain valid.</i> 					