EC CERTIFICATION

QUALITY ASSURANCE CERTIFICATE

Regulation (EU) 2017/745 for Medical Devices, Annex XI Part A

We hereby declare that a conformity assessment based on a production quality assurance system and technical documentation (excluding type-examination) has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

J H Orsing AB

Tornborgavägen 26, 253 68 Helsingborg, Sweden

Manufacturer SRN: SE-MF-000003934

Scope:

Dental instruments

Certificate Number:
28620149273

Revision:
00

Initial Certification Date:
15 May 2023

Certificate Decision Date:
15 May 2023

Certificate Issue Date:
15 May 2023

Certificate Expiry Date:
5 July 2027

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

PRODUCT LIST FOR CERTIFICATE

See attached product list

EXAMINATION AND TESTS PERFORMED

Technical Assessment Report Reference	**TD00192-01 J H Orsing AB UnoDent Disposable Vented Aspirator Tube**
Audit Report Reference	**Stage 1 audit ACTY-2022-533022**
	Stage 2 audit ACTY-2022-533025

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:
28620149273

Revision:
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MDR – Decision Report

Certificate No: 28620149273
Date: 15 May 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

J H Orsing AB
Attn: Tomas Skeppmark
Tornborgavägen 26,
SE-253 68 Helsingborg
Sweden

Purpose

Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex XI.
Expiry date on MDR certificate is set to be aligned with client´s audit cycle for ISO 13485:2016 certificate.

Activity

Audit Type	Location	Auditor Name	Audit Date
Stage 1 ACTY-2022-533022	Helsingborg	Mikael Hagelin	9 Nov 2022
Stage 2 ACTY-2022-533025	Helsingborg	Mikael Hagelin	14 – 26 Jan 2023

Technical Documentation Report	Assessor Name	Assessment Date
MDR TD Assessment Report_JH Orsing_Aspirator tubes_2023-04-24_final.signed	Lian Zhang	24 April 2023
Appendix 1_MDR CEAR_JH Orsing_Aspirator tubes_TD00192-01_2023-04-24.final.signed	Lian Zhang	24 April 2023

Scope of assessment

Dental instruments, Class IIa

Result

2 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.

All non-conformities noted during the technical documentation assessment(s) have been closed.

Certificate Valid from

15 May 2023

Conclusions/Decisions

Referring to the above, a Certificate of Conformance with the Medical Device Regulation 2017/745, Annex XI will be issued. The Certificate is valid for products specified in the “MDR – Product List”.

Follow-up assessments

Follow-up assessments are going to be performed once per year.

Appeals

Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Medical Notified Body AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Others

Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Medical Notified Body has the right to review this documentation.

Intertek Medical Notified Body AB
Notified Body MDR

Brian Mather
Certification Authority (Audit and TD Assessment)

PRODUCT LIST FOR CERTIFICATE

Issued to: J H Orsing AB

Certificate number: 28620149273

Certificate valid from: 2023-05-15

Product List Issue Date:
03 February 2025

Product	Classification and EMDN	Intended use[1]	Date Added
Dental instruments			
Basic UDI-DI: 739350799900KX			
L1000 - Hygoformic L Bio Lime green	Class IIa Q019001		2023-05-15
U1000 - Hygoformic White	Class IIa Q019001		2023-05-15
U100 - Hygoformic White	Class IIa Q019001		2023-05-15
U2000 - Hygoformic White	Class IIa Q019001		2023-05-15
UB1000 - Hygoformic Bio Green	Class IIa Q019001		2023-05-15
UB100 - Hygoformic Bio Green	Class IIa Q019001		2023-05-15
UB2000 - Hygoformic Bio Green	Class IIa Q019001		2023-05-15
UC10LG - Hygoformic Comfort Bio Lime green	Class IIa Q019001		2023-05-15
Basic UDI-DI: 739350799901KZ			
A100 - Angles Opaque	Class IIa Q019001		2023-05-15
A100LB - Angles Light blue	Class IIa Q019001		2023-05-15
A100UD - UnoDent Angles Opaque	Class IIa Q019001		2023-05-15
AB100 - Scantube Bio Green, 135 mm	Class IIa Q019001		2023-05-15
AT100 - Scantube White, 135 mm	Class IIa Q019001		2023-05-15
AV100BL - Scantube Vent Blue, 145 mm	Class IIa Q019001		2023-05-15
AV100LB - Scantube Vent Light blue, 145 mm	Class IIa Q019001		2023-05-15
AV100MG - Scantube Vent Mint green, 145 mm	Class IIa Q019001		2023-05-15

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Product	Classification and EMDN	Intended use[1]	Date Added
AV100OR - Scantube Vent Orange, 145 mm	Class IIa Q019001		2023-05-15
AV100PU - Scantube Vent Purple, 145 mm	Class IIa Q019001		2023-05-15
AV100 - Scantube Vent White, 145 mm	Class IIa Q019001		2023-05-15
AVB100 - Scantube Vent Bio Green, 145 mm	Class IIa Q019001		2023-05-15
B100 - Hygovac Bio White, 120 mm	Class IIa Q019001		2023-05-15
B100LG - Hygovac Bio Lime green, 120 mm	Class IIa Q019001		2023-05-15
BK100 - Scantube Black, 135 mm	Class IIa Q019001		2023-05-15
BL100 - Scantube Blue, 135 mm	Class IIa Q019001		2023-05-15
BS100 - Hygovac Short Bio White, 95 mm	Class IIa Q019001		2023-05-15
BS100LG - Hygovac Short Bio Lime green, 95 mm	Class IIa Q019001		2023-05-15
CVB100 - Medibase Vent Tubes Bio Green, 145 mm	Class IIa Q019001		2023-05-15
DP100 - Orbis Tubes Blue, 142 mm	Class IIa Q019001		2023-05-15
HJ25 - Hygo Jet	Class IIa Q019001		2023-05-15
LB100 - Scantube Light blue, 135 mm	Class IIa Q019001		2023-05-15
LC100 - Scantube Lilac, 135 mm	Class IIa Q019001		2023-05-15
LG100 - Scantube Lime green, 135 mm	Class IIa Q019001		2023-05-15
MG100 - Scantube Mint green, 135 mm	Class IIa Q019001		2023-05-15
OR100 - Scantube Orange, 135 mm	Class IIa Q019001		2023-05-15
PK100 - Scantube Pink, 135 mm	Class IIa Q019001		2023-05-15
PU100 - Scantube Purple, 135 mm	Class IIa Q019001		2023-05-15
PVB100 - Pelotte Vent Tubes Bio Green, 145 mm	Class IIa Q019001		2025-01-31
SPB1000 - Spotnix Bio	Class IIa Q019001		2023-10-06
SPB100 - Spotnix Bio	Class IIa Q019001		2023-10-06
T100LB - Top Dent T-Vac Light blue, 135 mm	Class IIa Q019001		2023-05-15

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620149273
Product list issue date: 03 February 2025

Product	Classification and EMDN	Intended use[1]	Date Added
T100WH - Top Dent T-Vac White, 135 mm	Class IIa Q019001		2023-05-15
TP25 - Hygo Tip	Class IIa Q019001		2023-05-15
TP25UD - UnoDent Tips	Class IIa Q019001		2023-05-15
TPXLB10 - Hygo Tip XL Bio	Class IIa Q019001		2023-05-15
TS100WH - Top Dent T-Vac Short White, 95 mm	Class IIa Q019001		2023-05-15
TV100BL - Top Dent S-Vac Vent Blue, 145 mm	Class IIa Q019001		2023-05-15
TVB100 - Top Dent S-Vac Vent Bio Green, 145 mm	Class IIa Q019001		2023-05-15
UD100LB - UnoDent Tubes Light blue, 135 mm	Class IIa Q019001		2023-05-15
UD100MG - UnoDent Tubes Mint green, 135 mm	Class IIa Q019001		2023-05-15
UD100OR - UnoDent Tubes Orange, 135 mm	Class IIa Q019001		2023-05-15
UD100WH - UnoDent Tubes White, 135 mm	Class IIa Q019001		2023-05-15
UV100LB - UnoDent Vent Tubes Light blue, 145 mm	Class IIa Q019001		2023-05-15
UV100MG - UnoDent Vent Tubes Mint green, 145 mm	Class IIa Q019001		2023-05-15
UV100WH - UnoDent Vent Tubes White, 145 mm	Class IIa Q019001		2023-05-15
UVB100 - UnoDent Vent Tubes Bio Green, 145 mm	Class IIa Q019001		2023-05-15
V100B - Hygovac Blue Blue, 140 mm	Class IIa Q019001		2023-05-15
V100G - Hygovac Green	Class IIa Q019001		2025-02-03
V100 - Hygovac White, 140 mm	Class IIa Q019001		2023-05-15
V100VG - Hygovac Vent Green	Class IIa Q019001		2025-02-03
V100V - Hygovac Vent White, 140 mm	Class IIa Q019001		2023-05-15
VB100V - Hygovac Vent Bio Green, 140 mm	Class IIa Q019001		2023-05-15
W100BL - EeziVac Tubes Blue, 135 mm	Class IIa Q019001		2023-05-15
W100 - EeziVac Tubes White, 135 mm	Class IIa Q019001		2023-05-15
W100MG - EeziVac Tubes Mint green, 135 mm	Class IIa Q019001		2023-05-15

[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.

Certificate number: 28620149273
Product list issue date: 03 February 2025

Product	Classification and EMDN	Intended use[1]	Date Added
WV100 - EeziVac Vent Tubes White, 145 mm	Class IIa Q019001		2023-05-15
WVB100 - EeziVac Vent Tubes Bio Green, 145 mm	Class IIa Q019001		2023-05-15
YW100 - Scantube Yellow, 135 mm	Class IIa Q019001		2023-05-15
Basic UDI-DI: 739350799902L3			
HS25 - Hygo Surge	Class IIa Q019001		2025-02-03
HS25XL - Hygo Surge XL	Class IIa Q019001		2025-02-03
MT25 - Microtip	Class IIa Q019001		2025-02-03

Mikael Hagelin
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Intertek Medical Notified Body AB, Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

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Product list issue date: 03 February 2025