

EC CERTIFICATION

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation restricted to the aspects of manufacture concerned with the conformity of the devices with sterility requirements - has been carried out following the requirements of EU Regulation 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.

Horizons International Corp

Zona Franca Zeta, La Valencia de Heredia, Costa Rica

Manufacturer SRN: CR-MF-000033925

Authorised Representative Name

ADVENA LIMITED

Tower Business Centre, 2nd Flr. Tower Street, Swatar, BKR 4013, Malta

Scope:

Sterility aspects of the Class Is devices as detailed in attached product list

Certificate Number:

28620150837

Revision:

00

Initial Certification Date:

22 May 2023

Date of Certification Decision:

22 May 2023

Certificate Issue Date:

22 May 2023

Certificate Expiry Date:

1 August 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

Last Audit report reference	Stage 1 audit ACTY-2020-448666
	Stage 2 audit ACTY-2018-303617

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

None

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES

Certificate Number:

28620150837

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Certificate No: 28620150837
Date: 22 May 2023
Handled by: Caroline Åman
E-mail: IMNB@intertek.com

Horizons International Corp
Attn: Rafic Saleh
Zona Franca Zeta,
La Valencia de Heredia,
Costa Rica

Purpose Assessment to issue a new certificate according to the Medical Device Regulation 2017/745, Annex IX.
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-2020-448666	Heredia, Costa Rica	Juan Zamora	28 Feb – 1 Mar 2023
	Stage 2 ACTY-2018-303617	Heredia, Costa Rica	Juan Zamora	27 – 28 Mar 2023

Scope of assessment Sterility aspects of the Class Is devices as detailed in attached product list

Result 0 non conformities were noted during the audit.

Certificate Valid from 22 May 2023

Conclusions/Decisions Referring to the above, a Certificate of Conformance with the Medical Device Regulation 2017/745, Annex IX 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

PRODUCT LIST FOR CERTIFICATE

Issued to: Horizons International Corporation
Certificate number: 28620150837
Certificate valid from: 2023-05-22

Product List Issue Date:
22 May 2023

Product	Classification and EMDN	Intended use ¹	Date Added
Class I Sterile Devices			
<i>Basic UDI-DI: 7453047401713</i>			
HIC-GDL-26 - Disposable TWISTER® PLUS Rotatable/Colon dia. 2.5MM; width 26MM;length 230CM	Class I(s)		2023-05-22
<i>Basic UDI-DI: 7453047401751</i>			
HIC-GDL-27 - Disposable TWISTER® PLUS Rotatable/Colon dia. 2.5MM; width 22MM;length 230CM	Class I(s)		2023-05-22
<i>Basic UDI-DI: 7453047401799</i>			
HIC-GDL-29 - Disposable TWISTER® PLUS Rotatable Polycatcher dia. 2.5MM; width 32MM;length 230CM	Class I(s)		2023-05-22
<i>Basic UDI-DI: 7453047401836</i>			
HIC-GDL-30 - Disposable TWISTER® PLUS Rotatable/Bronch. dia. 1.7MM; width 11MM;length 120CM	Class I(s)		2023-05-22
<i>Basic UDI-DI: 7453047401874</i>			
HIC-GDL-31 - Disposable TWISTER® PLUS Rotatable/Pediatric Gastro dia. 2.5MM; width 11MM;length 160CM	Class I(s)		2023-05-22
<i>Basic UDI-DI: 7453047402031</i>			
HIC-BHD-20 - Disposable Hexagonal Basket dia. 2.5MM; length 120CM;width 22MM	Class I(s)		2023-05-22
<i>Basic UDI-DI: 7453047402079</i>			

¹The 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
HIC-BHD-21 - Disposable Hexagonal Basket dia. 2.5MM; length 120CM; width 30MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047402116			
HIC-BHD-22 - Disposable Hexagonal Basket dia. 2.5MM; length 160CM; width 22MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047402154			
HIC-BHD-23 - Disposable Hexagonal Basket dia. 2.5MM; length 160CM; width 30MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047402192			
HIC-BHD-24 - Disposable Hexagonal Basket dia. 2.5MM; length 230CM; width 22MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047402239			
HIC-BHD-25 - Disposable Hexagonal Basket dia. 2.5MM; length 230CM; width 30MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047402277			
HIC-BHD-26 - Disposable Hexagonal Basket dia. 1.7MM; length 120CM; width 13MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047402314			
HIC-BHD-27 - Disposable Hexagonal Basket dia. 1.7MM; length 160CM; width 13MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403113			
HIC-CB-20 - Disposable Cytology Brush dia. 2.5MM; length 160CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403236			
HIC-CB-23 - Disposable Cytology Brush dia. 1.7MM; length 160CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403274			

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Certificate number: 28620150837

Product list issue date: 22 May 2023



Product	Classification and EMDN	Intended use ¹	Date Added
HIC-MB-1.0 - Microbiology Brushes dia. 1.8MM;length 120CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403311			
HIC-SI-20 - Disposable Cold Biopsy Forceps; tip dia. 2.5MM;length: 120CM; oval/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403359			
HIC-SI-21 - Disposable Cold Biopsy Forceps; tip dia. 2.5MM;length: 160CM; oval/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403397			
HIC-SI-22 - Disposable Cold Biopsy Forceps; tip dia. 2.5MM;length: 230CM; oval/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403434			
HIC-SI-23 - Disposable Cold Biopsy Forceps; tip dia. 1.7MM;length: 120CM; oval/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403472			
HIC-SI-24 - Disposable Cold Biopsy Forceps; tip dia. 1.7MM;length: 160CM; oval/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403519			
HIC-SN-20 - Disposable Cold Biopsy Forceps; tip dia. 2.5MM;length: 120CM; oval/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403557			
HIC-SN-21 - Disposable Cold Biopsy Forceps; tip dia. 2.5MM;length: 160CM; oval/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403595			
HIC-SN-22 - Disposable Cold Biopsy Forceps; tip dia. 2.5MM;length: 230CM; oval/no spike	Class I(s)		2023-05-22

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Certificate number: 28620150837

Product list issue date: 22 May 2023



Product	Classification and EMDN	Intended use ¹	Date Added
Basic UDI-DI: 7453047403632			
HIC-SIG-20 - Disposable Cold Biopsy Forceps; tip dia. 2.5MM;length: 230CM; alligator/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403670			
HIC-SIG-21 - Disposable Cold Biopsy Forceps; tip dia. 2.5MM;length: 160CM; alligator/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403717			
HIC-SIG-22 - Disposable Cold Biopsy Forceps; tip dia. 2.5MM;length: 120CM; alligator/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403755			
HIC-SIG-23 - Disposable Cold Biopsy Forceps; tip dia. 1.7MM;length: 120CM; alligator/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403793			
HIC-SIG-24 - Disposable Cold Biopsy Forceps; tip dia. 1.7MM;length: 160CM; alligator/no spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403830			
HIC-SNG-21 - Disposable Cold Biopsy Forceps; tip dia. 1.7MM;length: 120CM; alligator/spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047403878			
HIC-SNG-22 - Disposable Cold Biopsy Forceps; tip dia. 1.7MM;length: 160CM; alligator/spike	Class I(s)		2023-05-22
Basic UDI-DI: 7453047404752			
HIC-GD-20 - Disposable Graspers 3 Prongs/No Loop dia. 2.5MM; length 120CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047404790			

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Product list issue date: 22 May 2023



Product	Classification and EMDN	Intended use ¹	Date Added
HIC-GD-21 - Disposable Graspers 3 Prongs/No Loop dia. 2.5MM; length 160CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047404837			
HIC-GD-22 - Disposable Graspers 3 Prongs/No Loop dia. 2.5MM; length 230CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047404875			
HIC-GD-23 - Disposable Graspers 3 Prongs/No Loop dia. 1.7MM; length 120CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047404912			
HIC-GD-24 - Disposable Graspers 3 Prongs/No Loop dia. 1.7MM; length 160CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047404950			
HIC-GD-25 - Disposable Graspers 4 Prongs/No Loop dia. 2.5MM; length 230CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047404998			
HIC-GDL-25 - Disposable Graspers 4 Prongs/with Loop dia. 2.5MM; length 230CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405032			
HIC-GDL-21 - Disposable Graspers 4 Prongs/with Loop dia. 2.5MM; length 160CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405070			
HIC-GDL-22 - Disposable Graspers 3 Prongs/with Loop dia. 2.5MM; length 230CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405117			
HIC-CB-21 - Disposable Cytology Brush dia. 2.5MM;length 230CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405155			
HIC-CB-22 - Disposable Cytology Brush dia. 1.7MM;length 120CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405193			

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Product	Classification and EMDN	Intended use ¹	Date Added
HIC-BED-20 - Disposable Elliptical Basket dia. 2.5MM; length 120CM; width 22MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405230			
HIC-BED-21 - Disposable Elliptical Basket dia. 2.5MM; length 120CM; width 30MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405278			
HIC-BED-22 - Disposable Elliptical Basket dia. 2.5MM; length 160CM; width 22MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405315			
HIC-BED-23 - Disposable Elliptical Basket dia. 2.5MM; length 160CM; width 30MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405353			
HIC-BED-24 - Disposable Elliptical Basket dia. 2.5MM; length 230CM; width 22MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405391			
HIC-BED-25 - Disposable Elliptical Basket dia. 2.5MM; length 230CM; width 30MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405438			
HIC-BED-26 - Disposable Elliptical Basket dia. 1.7MM; length 160CM; width 13MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405476			
HIC-BED-27 - Disposable Elliptical Basket dia. 1.7MM; length 160CM; width 13MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405513			

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Product	Classification and EMDN	Intended use ¹	Date Added
HIC-BHDP-23 - Disposable Hexagonal Basket with Injection port dia. 2.5MM; length 160CM; width 30MM	Class I(s)		2023-05-22
Basic UDI-DI: 745304740551			
HIC-BHDP-25 - Disposable Hexagonal Basket with Injection port dia. 2.5MM; length 230CM; width 30MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405919			
HIC-BEDP-23 - Disposable Elliptical Basket with Injection port dia. 2.5MM; length 160CM; width 30MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047405957			
HIC-BEDP-25 - Disposable Elliptical Basket with Injection port dia. 2.5MM; length 230CM; width 30MM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047406251			
HIC-CB-24 - Disposable Cytology Brush dia. 1.7MM; length 120CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047406299			
HIC-CB-25 - Disposable Cytology Brush with needle tip dia. 1.9MM; length 120CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047406336			
HIC-CB-26 - Disposable Cytology Brush without needle tip dia. 1.9MM; length 120CM	Class I(s)		2023-05-22
Basic UDI-DI: 7453047406374			
HIC-GDL-28 - Disposable TWISTER® PLUS Rotatable Polycatcher dia. 2.5MM; width 13MM; length 230CM	Class I(s)		2023-05-22

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