

Declaration of Conformance

for KOVA® Plastics, KOVA® poc System Packs

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009

The undersigned declares that the products named in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Names:	General Specimen microscopy slide IVD, single use, Centrifuge tube/caps IVD, User induced pipette {See ANNEX - Product Listing/Schedule for definitive product list}
Manufacturer:	Alltrista Plastics LLC., 20 Setar Way, Reedsville PA 17084, USA
Variants:	N/A
Intended Use:	Disposable Plastic accessories used for collection, transport of clinical specimens for analysis.
Intended User:	Professional use
IVD Directive Category:	General
Notified Body:	N/A
CE Certificate Reference:	N/A
IVD Directive Assessment route:	Annex III of the Directive 98/79EC
EU Authorized Representative:	Advena Limited. Tower Business Centre, 2 nd Floor, Tower Street, Swatar BKR 4013 Malta

Name: Tiffany Orndorf

Position: Quality Manager

Signed:



Date: 10/25/2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

Appendix I - Applicable Standards

Standard/Document Name	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
EN ISO 13485:2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices - Application of Risk Management to Medical Devices

Appendix I – Product Listing

Part # Catalog Number	Product Name	GMDN Code
87118E	KOVA slides II w/o grids	57925
87100E	KOVA slides II w/ grids	57925
87135E	KOVA Petters	43375
87137E	KOVA Super Tubes	43761
87139E	KOVA Caps	62229
87140	KOVA Automation Tubes	43761
87141E	KOVA Ko-Lec-Pack	57925, 43761 ,43375, 62229
87144E	KOVA Glasstic Slide 10 w/grids	57925
87144F	KOVA Glasstic Slide 10 w/grids	57925
87146E	KOVA Glasstic Slide w/o grids, 1000 determinations	57925
87157E	KOVA Glasstic Slide w/o grids, 500 determinations	57925
87153E	KOVA System Super Pack, 1000 w/caps	57925, 43761 ,43375, 62229
87154E	KOVA System Super Pack, 1000 w/o caps	57925,43761, 43375
87155E	KOVA System Pac II	57925,43761, 43375
87156E	KOVA System Value Pack 500	57925,43761, 43375
87161E	KOVA System Evaluation Pac	57925,43761, 43375
87162E	KOVA System Super Pack 1000 w/grids	57925,43761, 43375
88100	KOVA – Poc System Pack	57925,43761, 43375
BVS100H	Kit Fast read 102, 1000 determinations	57925

Version History

Version	Compiled by	Date	Description
1.0	Tiffany Shipkowski	5/19/2021	First issue
2.0	Tiffany Orndorf	10/25/2021	Addition of 87144F