



recoltoare cu vid pentru Biochimie/Imunologie, siliconate, 8 ml, plastic, 16x100 mm, dop rosu, cutii x100, cu doua etichete autoadezive cu cod unic de identificare a pacientului, a doua eticheta este destinata pentru a fi aplicata pe tubul secundar cand se portioneaza sangele recoltat in tubul primar, cod C48VT1008DL, xnl, todylaboratories®, CE mark

Catre: Bio Analitica SRL
In atentie: D-lui Ghenadie Rusu
Ref: licitatie

SCRISOARE DE CLARIFICARE

Subsemnatii, Tody Laboratories INT SRL, declaram ca recoltoarele cu vid (cod C48VT1008DL) oferate de catre Bio Analitica SRL in licitatie organizata de catre Agentia Nationala pentru Siguranta Alimentelor, au denumirea tehnica de tutburi de recoltare de 8 ml, deoarece acestea sunt marcate cu gradatii pana la volumul de 8 ml. In realitate, tuburile au acelasi volum ca si tuburile cu calificarea generala de 9 ml, avand dimensiunile de 16x100 mm.

Data: 03.05.2019

Semnatura:
Reprezentant: ȘTEFĂNESCU ADRIAN





EC DECLARATION OF CONFORMITY

In conformity with Annex III of the 98/79/EC Directive of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, we:

Manufacturer **Tody Laboratories Int. SRL**
22nd Vadul Moldovei street, 1st sector, Bucharest, Romania

Declare on our own responsibility that the following in vitro diagnostic medical devices:

Description: Vacuum blood collection tubes, according to annex 1
Code: according to annex 1

Are fulfilling the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council with regards to the in vitro diagnostic medical devices, which is applicable for these products.

Classification: Other in vitro diagnostic medical devices (not included in Annex II of the 98/79/EC Directive)

Conformity assessment route: Annex III of the 98/79/EC Directive

EDMA code : 51 01 01 01, 51 01 01 02,
51 01 01 03, 51 01 01 04,
51 01 01 09

GMDN Code: 57895

Applicable standards: EN ISO 13485:2012, EN ISO 23640: 2015, EN ISO 14971:2012, SR EN 14820: 2005, SR EN ISO 18113-3:2012, SR EN ISO 11607-1:2009, SR EN ISO 11137-1:2015, EN ISO 15223-1:2012.

Place and date: Bucharest, Romania, 01.05.2017



Diana Rîpeanu
General Manager
Tody Laboratories Int. SRL

TODY LABORATORIES INT. SRL

Annex 1 – Vacuum blood collection tubes

Code	Description	Specification
C48VT1013DL	Vacuum Tubes® EDTA K2 purple tube, 2 ml	PET
C48VT1014DL	Vacuum Tubes® EDTA K2 purple tube, 3 ml	PET
C48VT1015DL	Vacuum Tubes® EDTA K2 purple tube, 4 ml	PET
C48VT1016DL	Vacuum Tubes® EDTA K2 purple tube, 6 ml	PET
C48VT1017DL	Vacuum Tubes® EDTA K3 purple tube, 2 ml	PET
C48VT1018DL	Vacuum Tubes® EDTA K3 purple tube, 3 ml	PET
C48VT1019DL	Vacuum Tubes® EDTA K3 purple tube, 4 ml	PET
C48VT1020DL	Vacuum Tubes® EDTA K3 purple tube, 6 ml	PET
C48VT1001DL	Vacuum Tubes® Gel & Clot Activator yellow tube, 3 ml	PET
C48VT1002DL	Vacuum Tubes® Gel & Clot Activator yellow tube, 5 ml	PET
C48VT1003DL	Vacuum Tubes® Gel & Clot Activator yellow tube, 8 ml	PET
C48VT1004DL	Vacuum Tubes® Lithium Heparin green tube, 4 ml	PET
C48VT1005DL	Vacuum Tubes® Lithium Heparin green tube, 6 ml	PET
C48VT1012DL	Vacuum Tubes® Potassium Oxalate/Sodium Fluoride grey tube, 3 ml	PET
C48VT1009DL	Vacuum Tubes® PT (Coagulation) double layer 3.2% blue tube, 1.8 ml	PET
C48VT1010DL	Vacuum Tubes® PT (Coagulation) double layer 3.2% blue tube, 2.7 ml	PET
C48VT1011DL	Vacuum Tubes® PT (Coagulation) single layer 3.2% blue tube, 4.5 ml	Glass
C48VT1021DL	Vacuum Tubes® ESR Sodium Citrate black tube, 1.6 ml	Glass
C48VT1022DL	Vacuum Tubes® ESR Sodium Citrate black tube, 1.8 ml	Glass
C48VT1023DL	Vacuum Tubes® ESR Sodium Citrate black tube, 2 ml	Glass
C48VT1026	Vacuum Tubes® Clot activator red tube, 0.5 ml	PP
C48VT1027	Vacuum Tubes® EDTA K3 purple tube, 0.5 ml	PP
C48VT1028	Vacuum Tubes® Heparin green tube, 0.5 ml	PP
C48VT1029	Vacuum Tubes® Gel & Clot Activator yellow tube, 0.5 ml	PP
C48VT1006DL	Vacuum Tubes® Procoagulation Clot activator red tube, 4 ml	PET
C48VT1007DL	Vacuum Tubes® Procoagulation Clot activator red tube, 6 ml	PET
C48VT1008DL	Vacuum Tubes® Procoagulation Clot activator red tube, 8 ml	PET
C48VT1024	Vacuum Tubes® ESR Rack	