



DECLARATION OF CONFORMITY

Product Family TOTAL AND FREE PROSTATE SPECIFIC ANTIGEN (PSA and FPSA)

Specific Product Details						
Product Description	Item # ELISA	Item # CLIA	EDMS Code	GMDN ELISA Code	GMDN CLIA Code	Risk Class
Total PSA Test System	2125-300A 2125-300B	2175-300A 2175-300B	12.03.01.32.00	54664	54665	High/ List B
Total PSA Extra Sensitive Test System	8725-300A 8725-300B	8775-300A 8775-300B	12.03.01.32.00	54664	54665	High/ List B
Free PSA Test System	2325-300A 2325-300B	2375-300A 2375-300B	12.03.01.33.00	54668	54669	High/ List B
Cancer VAST Test System	8425-300B 8425-300D 8425-300E	8475-300B 8475-300D 8475-300E	12.03.01.32.00	54664	54665	High/ List B
Multi Ligand Control	ML-300B	ML-300B	12.03.01.32.00	38207	38207	High/ List B

Manufacturer

Name Monobind Inc.
Address 100 North Pointe, Lake Forest, CA 92630
Country United States

Representative

Name CEpartner4U BV,
Address Esdoornlaan 13, 3951DB Maarn
Country The Netherlands
Telephone +31 (0)6 – 516.536.26

Notified Body

Name NSAI
Body ID Number 0050
CE Cert # 304.1006
Registration # NL-CA002-2011-23306

Means of Conformity

Monobind Inc. declares that the product listed is in conformity with the Annex IV, IVD Type List B essential requirements and provisions of Council Directive: 98/79/EC

And is in conformance with the following standards:

EN 13612:2002	EN 15223-1:2016	EN ISO 14971:2019
EN ISO 18113:2011	EN 13641:2002	EN ISO 23640:2015
Under the principles of	EN ISO 13485:2016	

Signature

Place and effective date

Monobind Inc.

January 30, 2021 revision 04

Signature

Name

Tony Shatola

Title

QA Director