EC DECLARATION OF CONFORMITY

***In vitro* Diagnostic Medical Devices in accordance with Directive 98/79/EC**

Manufacturer:	Türklab Tıbbi Mal. San. Tic. A.Ş.
Head Office:	Sasalı Merkez Mah. Doğa Dostları Sitesi 131 Sokak No: 2/5 Çiğli / İzmir - Turkey
Manufacturing Side:	ITOB 10031 Sokak No: 15 Tekeli - Menderes / Izmir - Turkey
Product:	Anti-HIV 1/2 Test
Brand:	Rapidan® Tester, Toyo®, Info®, Labmen®
Classification:	Annex II List A, 98/79/EC
Conformity Assessment Route:	Annex IV

We, herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for *In-Vitro* Diagnostic Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 15223:2016 EN ISO 18113-2:2011 EN ISO 18113-3:2011 EN ISO 23640:2015 EN 13612:2002
Notified Body:	Polish Centre for Testing and Certification (PCBC), ul. Klobucka 23a 02-699 Warszawa Poland (Notified Body # 1434)
Start of CE Marking:	29.08.2008
Revision No:	6
Place, Date of Issue:	Izmir, 16.07.2018
Signature	Dr. Şahin Yağlıdere, Md General Manager

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