

EC Declaration of Conformity

According to Annex III of the IVD Directive 98/79/EC

This is to certify that following IVD (In-Vitro Diagnostics) products:

Labosel and Debooglu and Debomed plastic medical and laboratory consumables listed in the attached Device Schedule,

Classified as: 'all other IVD Medical Devices' according to Annex I rules,

Manufactured by: **Debooglu İnş. Mim. Tar. Ve Gıda A.Ş.**
Antakya Organized Industrial Zone, Cakallı Mah. 14 Nolu Yol, No:1 Belen, Hatay, Turkey, 31350

1. Comply with all essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the IVD Directive.
2. Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:
 - a. Availability of the technical documentation set in Annex III (section 3), allowing the assessment of the conformity of the product with the requirements of the Directive.
 - b. The manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
 - c. The manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).
3. Debooglu A.Ş. has a Quality System in place based on ISO 13485:2016
4. This Declaration of Conformity is signed below, certifying that the requirements of Annex I and Annex III have been met and documented.

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Labosel™ / DeboMed™
Debooglu AS

Device Schedule

Labosel™ and DebMed™ includes the following consumables.

Name	Detail
Automatic Pipette Tips	Yellow: 5 – 200 uL, Blue: 100 – 1000 uL
Microcentrifuge Tube (Eppendorf)	1.5 mL, with lid
Test Tube (Polystyrene)	5 mL 12x75 mm cylindrical bottom
Test Tube (Polystyrene)	10 mL 16x100 mL conical bottom
Test Tube Caps	For 12x75 mm and 16x100 mm tubes
Urine Specimen Containers	Sterile and Non-Sterile
Urine Specimen Containers	With Pochette and Not sterilized
Gaita/Stool/Faeces Containers	With spoon and screw cap, Sterile and Non-Sterile
Gaita/Stool/Faeces Containers	50 mL, pink
Centrifuge Tube (Falcon Tube)	15 mL, screw cap, Polypropylenec, Sterile and Non-Sterile
End of Schedule	

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