

# 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.

**Authorised Representative:** Debooglu İnş. Mim. Tar. Ve Gıda AS  
Antakya Organized Industrial Zone, Cakallı Mah. 14 Nolu Yol,  
No:1 Belen, Hatay, Turkey, 31350  
Tel: +90 533 680 0888

.....  
Mehmet H. Debooglu  
General Manager (Bsc Engineering)

Date: 11.01.2022

**debooglu**  
İNŞAAT MİMARLIK TARIM VE GIDA ANONİM ŞİRKETİ  
Cakallı Mah. 14 Nolu Yol Cad. No: 1 Belen/Hatay  
T: +90 533 680 08 88 Belen VD: 272 081 086  
Mersis No: 0272 0810 8600 0001

Document: 30.1905.GS31

Labosel™ / DeboMed™  
Debooglu AS

## Device Schedule

Labosel™ and DeboMed™ 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 mm 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***	

**debooglu**  
İNSAAT MİMARLIK TARIM VE GIDA ANONİM ŞİRKETİ  
Çakıllı Mah. 14 No.lu Yol Cad. No: 1 Beien/Hatay  
T: +90 533 680 08 88 Beien VD: 272 061 0860  
Mersis No.: 0272 0810 8600 0001