



# Declaration of Conformity



**According to the 98/79/EC In-Vitro Diagnostic  
Medical Devices Directive (IVD), § 25 MPG General Obligation  
Medical Devices Act, Germany/EU**

Biosepar GmbH, manufacturer of **ParasiTrap®** parasitological diagnostic in-Vitro Medical Device System, declares that all mentioned tubes and fluids, complies with the European Directive 98/79/EC (IVD)

The present conformity declaration, as stated in Other Devies except Annex II of the 98/79/EC Directive is based upon the folowing requirements:

Biosepar GmbH has a Quality Management System in place, which complies with ISO 9001 and Envirenment Management System ISO 14000 regulations and agrees to develop, implement and maintain the Quality Management System to ensure continued adequacy and efficacy.

### **Working Procedures and instructions for**

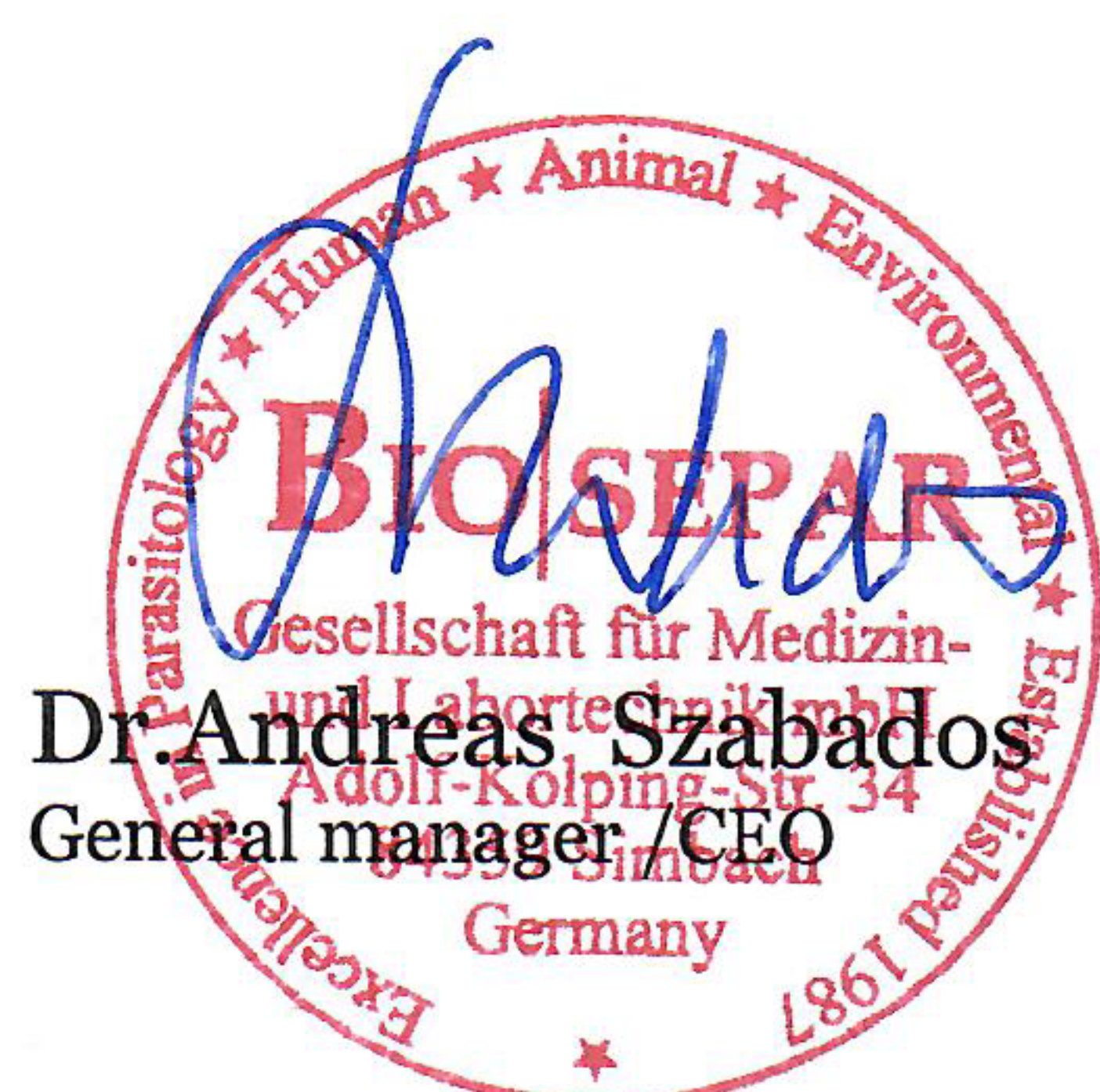
- Design process control
- Manufacturing process control
- Tests and Checks

### **System documentation**

- Technical documents
- Risk analysis
- User manuals
- Service manuals
- Planing and controls of aerosol emissions and hygienic conditions
- Reduction and control of energy power consumption in all working procedures
- Development, research and use of new, environmental friendly materials for all products
- Recycling and waste materials management

Product description	Product code	EDMA code	Category
ParasiTrap® SAF Kit all in one	8486 SAF	1405010100, 1405	Other Parasitology
ParasiTrap® ECO Kit all in one	8486 ECO	1405010100, 1405	Other Parasitology
ParasiTrap® AF Kit all in one	8486 AF	1405010100, 1405	Other Parasitology
ParasiTrap® Bailenger Kit all in one	8486 Bailenger	1405010100, 1405	Other Parasitology
ParasiTrap® Staining, separation	8487/CM	1405019000, 140501	Other Parasitology
ParasiTrap® Processing I tube	8490/ECO	140501, 1405	Other Parasitology
ParasiTrap® ECO Processing medium	8487/A/ECO	140501, 1405	Other Parasitology
ParasiTrap® Processing tube II	8491	14050100 149001	Other Parasitology
ParasiTrap® Staining, separation	8487/C	140501900, 140501	Other Parasitology

This Declaration of Conformity is signed below, certifying these requirements have been met.



Dr. Andreas Szabados  
General manager / CEO



Simbach, 11<sup>th</sup> October 2022

**Biosepar GmbH, Adolf-Kolpingstr. 34,  
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