TECHLAB®

PROVEN PERFORMANCE IN
GI DISEASE DIAGNOSTICS

# Declaration of Conformity

| PRODUCT IDENTIFICATION | |
|---|---|
| **Product Name** | **Model/Number** |
| LACTOFERRIN SCAN®<br>Including all of the corresponding components | T5009, 30351 |

| MANUFACTURER | | |
|---|---|---|
| **Name of Company** | **Address** | **Representative** |
| TECHLAB, Inc. | 2001 Kraft Dr<br>Blacksburg, VA 24060-6358<br>USA | Donna T. Link – Director Regulatory and Compliance |

| AUTHORIZED REPRESENTATIVE | | |
|---|---|---|
| **Name of Company** | **Address** | **Telephone/Email** |
| Emergo Europe | Prinsessegracht 20<br>2514 AP The Hague<br>The Netherlands | +31.70.345.8570 - phone<br>+31.70.346.7299 - fax<br>europe@emergogroup.com |

| CONFORMITY ASSESSMENT | | |
|---|---|---|
| **Device Classification** | **Route to Compliance** | **Standards Applied** |
| Class: Self-Certify | Annex III of IVDD 98/79/EC Council Directive | ISO 13485:2003<br>ISO 13485:2012 |

**TECHLAB, Inc.** declares that the above-mentioned products meet the provision of the Council Directive 98/79/EC for *In Vitro* Diagnostic Medical Devices and Directive 98/79/EC as transposed in the national laws of the Member States.

**COMPANY REPRESENTATIVE:** Donna T. Link
**TITLE:** Director Regulatory and Compliance

**SIGNATURE:** Donna Link

**DATE:** 29/06/2017
DD/MM/YYYY