

Certificate of CE-Registration

This is to certify that, in accordance with the *In Vitro* Diagnostic Medical Device Directive 98/79/EC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

Glycominds Diagnostics (2014) Ltd. 16 Hatidhar St., P.O. Box 4131 P.O. Box 4131, 43652 RAANANA ISRAEL

as stipulated and demanded by the aforementioned Directive. The European Databank on Medical Devices (EUDAMED) is established as of May 1, 2011. The German Competent Authority is notified of the manufacturer's *in vitro* diagnostic medical devices and has allocated registration numbers shown in:

Annex A dated September 30, 2015

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the *in vitro* diagnostic medical devices fulfill the applicable requirements of Directive 98/79/EC. In compliance with German law, a safety officer has been appointed for Germany.

September 30, 2015

Joy Grimm

Senior Consultant - IVD

MDSS GmbH

Annex A: September 30, 2015

Manufacturer: Glycominds Diagnostics (2014) Ltd.



THE FOLLOWING NOTFICATI	ONS WERE SUBMITTED AFTER EUDAMED IMPLEMENTATION
Registration No.:	DE/CA09/0170/IVD/5554
EDMA Code:	12 10 90 19
EDMA Description:	Saccharomyces cerevisiae Antibodies
Risk Class:	"Other"
EC Certificate:	N/A
Certificate Expiry:	N/A
Notified Device Name(s):	IBDX® gASCA IgG; IBDX® ALCA IgG; IBDX® ACCA IgA; IBDX®
	AMCA IgG
Manufacturer's Device Identification	
IBDX® gASCA IgG	\$701100
IBDX® ALCA IgG	C702100
IBDX® ACCA IgA	L703200
IBDX® AMCA IgG	M704100

