DOC REV. 6 DATE 11/2018

DICHIARAZIONE DI CONFORMITÀ "CE"
PER DISPOSITIVI MEDICI DIAGNOSTICI IN VITRO
EC Declaration of Conformity for IN VITRO DIAGNOSTIC MEDICAL DEVICES

MANUFACTURER:	*DELTA BIOLOGICALS S.r.l.* *VIA NICARAGUA 12/14 – POMEZIA - ROME - ITALY*
EUROPEAN REPRESENTATIVE:	*NONE*
PRODUCT:	***HBsAg One Step, HBsAb, HBcAb, HBc IgM, HBe Ag&Ab, HDV Ab, HDV Ag, HDV IgM, HCV Ab***
CODE:	*4210-4211; 4215; 4220; 4225; 4230; 4235; 4240; 4245; 4250-4251*
CLASSIFICATION:	*ANNEX II - LIST A*
CONFORMITY ASSESSMENT PROCEDURE:	*ANNEX IV*

Digitally signed by Munteanu Iuliana
Date: 2019.06.19 16:02:24 EEST
Reason: MoldSign Signature
Location: Moldova

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC DEVICES AND ARE IN CONFORMITY WITH THE FOLLOWING STANDARDS:

EN ISO 13485:2012 MEDICAL DEVICES - QUALITY MANAGEMENT SYSTEMS - REQUIREMENTS FOR REGULATORY PURPOSES
EN ISO 14971:2012 MEDICAL DEVICES - APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES
EN ISO 18113-2:2011 IN VITRO DIAGNOSTIC MEDICAL DEVICES - INFORMATION SUPPLIED BY THE MANUFACTURER (LABELLING) – PART 2: IN VITRO DIAGNOSTIC REAGENTS FOR PROFESSIONAL USE
EN ISO 15223-1:2017 MEDICAL DEVICES - SYMBOLS TO BE USED WITH MEDICAL DEVICE LABELS, LABELLING AND INFORMATION TO BE SUPPLIED - PART 1: GENERAL REQUIREMENTS
EN 13612:2002 PERFORMANCE EVALUATION OF IN VITRO DIAGNOSTIC MEDICAL DEVICES
EN 23640:2015 IN VITRO DIAGNOSTIC MEDICAL DEVICES -- EVALUATION OF STABILITY OF IN VITRO DIAGNOSTIC REAGENTS
EN 13641:2002 ELIMINATION OR REDUCTION OF RISK OF INFECTION RELATED TO IN VITRO DIAGNOSTIC REAGENTS.

NOTIFIED BODY:	INSTITUT PRO TESTOVÁNÍ A CERTIFIKACI, A.S., T. BATI 299- LOUKY– 763 02 ZLIN (CZECH REPUBLIC)
NOTIFIED BODY NUMBER:	1023
CERTIFICATE:	N. 17 0127 QS/NB
FIRST ISSUE:	--
START OF CE-MARKING:	OCTOBER 2011
CURRENT EMISSION:	17-03-2017
PLACE, DATE OF ISSUE:	POMEZIA, 20-03-2017
NAME LEGAL RAPRESENTATIVE:	DR. BRAVETTI DORIANO
SIGNATURE	
LEGAL REPRESENTATIVE:	