EXPRESS DIAGNOSTICS INT'L. INC.

EC Declaration of Conformity

Manufacturer: Express Diagnostics International, Inc.	***Address:*** ***1550 Industrial Drive*** ***Blue Earth, Minnesota*** ***56013 USA***
Device Group: Drug of Abuse Screening Device	
Device Family: 700 Series	
Device Name: Flat Cup Urine DOA Screen	
***Product Part Number(s):* 70801-6A SI: Screen Cup 8 + A + AD AMP500 COC MDMA MET500 MTD OPI300 THC BUP & Alcohol & pH SG OX CR NI GL**	
Device Classification Per IVDD: Per Annex II of the IVDD; Non-list A, Non-list B and Non-self test	
Year of Manufacturer: 2013	
European Representative: ***CEpartner4U*** ***Esdoornlaan 13*** ***3951 DB Maarn*** ***The Netherlands*** ***31 (0) 343 442 524*** ***www.cepartner4u.nl***	
Annex II Notified Body: BSI	
Declaration: Express Diagnostics hereby declares that the medical devices specified above to which this declaration relates to the IVDD in conformity with the essential requirements of Council Directive 98/79/EC Article 9 (1).	
Declaration Based On: Self declaration	
Prepared By: Quality Steering Team and Regulatory Affairs	
_____ ***(Gary Jueneman, VP/GM)***	_____ ***(Date of Approval)***
_____ ***(Martin Lueders, Director of Quality Systems)***	_____ ***(Date of Approval)***

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1550 Industrial Drive, Blue Earth, MN 56013 • 507-526-3951 • 888-466-8433 • Fax 888-444-5754 • drugcheck.com
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