

EC Declaration of Conformity

Manufacturer: DFI Co., Ltd.

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European Representative: DONGBANG ACUPRIME

1 The Forrest Units, Hennock Road East Exeter, EX2 8RU, UK

Tel: 0044-1392-829500, Fax: 0044-1392-823232

Product: Urine Chemistry Analyzer

Model : CYBOW Reader 300

Classification : Others (not listed in the Annex II, IVDD 98/79/EC)

Conformity Assessment route: Annex III, IVDD 98/79/EC

EDMA code: 21. 01. 10. 01

GMDN code: 57860

We herewith declare that the above mentioned products meet the provisions of the Council Directives 98/79/EC for In Vitro Diagnostic medical devices.

All supporting documentation is retained under the premises of the manufacturer.

Applicable Harmonized Standards:

EMC: Certificate by TUV Product (2009-AUG- 03)

EN 61326-2-6:2006 / EN 61000-3-2:2006 / EN 61000-3-3/A2:2005

Safety: Certificate by TUV Product Service (2009-AUG- 20)

EN 61010-1:2001

Start of CE-marking: 2009-AUG

Place, Issuing date: Gimhae-si, 2011-MAR-15



Yun Jung Geon
President on behalf of DFI Co., Ltd.