

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 Reagent Strips

Model : CYBOW Series

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

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

EDMA code: 11.70.02.02

GMDN code: 54514

We DFI Co., Ltd. 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.

Standards Applied: EN 13612:2002, EN 13640:2002, EN ISO 18113-2

EN 980:2008, ISO 13485:2003

Start of CE-marking: 2002-OCT

Place, Issuing date: Gimhae-si, 2002-OCT-20



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