



DECLARATION OF CONFORMITY EC

in accordance with the Law No. 22/1997 Coll., Sb., § 13: in the wording of the Law No.71/2000 Coll., of the Law No. 102/2001 Coll., of the Law No. 205/2002 Coll., of the Law No. 226/2003 Coll., of the Law No. 277/2003 Coll., of the Law No. 186/2006 Coll., of the Law No. 229/2006 Coll., of the Law No. 481/2008 Coll., of the Law 281/2009 Coll., and of the Law No. 490/2009 Coll.

APPLIANCE (PRODUCT) NAME:	Menstruation cup
TYPE:	MK
EXECUTIONS (OTHER SPECIFICATION):	10 and 15
classification - class:	I
sanitary appliance made on order:	NO
sanitary appliance:	NON-STERILE, FOR MEASURING PURPOSES
MANUFACTURER	
NAME:	YUUKI CUP BETA Trading Company, Ltd.
ADDRESS:	46005 Liberec, Hvězdná St. 484
Id. No.:	25407457
Tax Id. No.:	CZ 25407457

declares on its own sole responsibility that the below indicated appliance complies with all pertinent provisions of the concerned

The Government Decree No. 336/2004 Coll., establishing technical requisites upon sanitary appliances and amending the Government Decree No. 251/2003 Coll., amending certain Government Decrees executing the Law. No. 22/1997 Coll., of technical requisites upon products and of the amendment and complementation of some Laws in the wording of later regulations, in the wording of the Government Decree No. 212/2007 Coll., GD No. 245/2009 Coll. (93/42/EEC, 2003/32/EC),

and the respective regulations and standards following from the said Decree (directive)

DESCRIPTION	FUNCTION
The cup is made of medical grade silicone.	The menstruation cup is a hygienic aid serving to entrap menstruation blood.

List of employed technical regulation and harmonised standards

ČSN EN ISO 10993-5 Biological assessment of sanitary aids – Section 5: Tests for cytotoxicity by the method in vitro

Procedure chosen for assessing the conformity

Assessment of the conformity under the conditions determined by the manufacturer or the distributor. Law No. 22/1997 Coll., as amended, § 12 sect. 3, letter a)

Name, address and identification number of the notified person who has performed the EC testing of the type, and the number of the EC certificate of testing of the type.

The referred appliance is not subject to obligatory testing by an authorised testing station.
Person entrusted with assembling the technical documentation: Ing. Petr Vrána, business premises - 61400 Brno, Proškovo nám. 21

Data of the identity of the person authorised to elaborate the declaration on behalf of the manufacturer or of his authorised representative, and the signature of this person.

place:	Liberec	Name:		Position:		Signature:	
date:	Aug 5, 2010						



Technical documentation

for the EC Declaration of Conformity in accordance with the Law No. 22/1997 Coll., Sb., § 13: in the wording of the Law No. 71/2000 Coll., of the Law No. 102/2001 Coll., of the Law No. 205/2002 Coll., of the Law No. 226/2003 Coll., of the Law No. 277/2003 Coll., of the Law No. 186/2006 Coll., of the Law No. 229/2006 Coll., of the Law No. 481/2008 Coll., of the Law 281/2009 Coll., and of the Law No. 490/2009 Coll.

The E. C. Declaration of Conformity is assessed in accordance with the principal requirements of the Government Decree:

The Government Decree No. 336/2004 Coll., establishing technical requisites upon sanitary appliances and amending the Government Decree No. 251/2003 Coll., amending certain Government Decrees executing the Law. No. 22/1997Coll., of technical requisites upon products and of the amendment and complementation of some Laws in the wording of later regulations, in the wording of the Government Decree No. 212/2007 Coll., GD No. 245/2009 Coll. (93/42/EEC, 2003/32/EC).



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Elaborated by:	AKPTESTING - Ing. Petr Vrána
No. of technical documentation:	CRW99 498
object of business:	Advisory and consulting services in the area of machines and machinery
address for invoicing:	Jiráskova 9, 602 00 Brno
business premises:	AKPTESTING - Proškovo nám. 21, 61400 Brno
Id.No.:	68613954
Tax Id. No.:	CZ551212374

