

Hartalega Sdn.Bhd.

SUBJECT : TECHNICAL FILE NITRILE EXAMINATION GLOVES	Doc.No.	:	HSB-TF-002
	Rev.No.	:	5
	Dated Issued	:	22 th March 2010
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DECLARATION OF CONFORMITY

MANUFACTURER : Hartalega Sdn.Bhd.
C-G-9, Jalan Dataran SD1, Dataran SD
PJU, Bandar Sri Damansara
52200 Kuala Lumpur
MALAYSIA

FACILITY: No.7,Kawasan Perusahaan Suria,
45600 Bestari Jaya,
Selangor Darul Ehsan
MALAYSIA

EUROPEAN REPRESENTATIVE : Medical Device Safety Service GmbH (MDSS)
Schiffgraben 41,D-30175 Hannover,
Germany.

PRODUCT : Nitrile Examination Gloves

CLASSIFICATION : Class 1,According to Annex IX of Directive 93/42/EEC

CONFORMITY ASSESMENT ROUTE : Annex VII

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC FOR MEDICAL DEVICES,ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED : ISO 9001:2008
ISO 13485 : 2003
EN 455-1 : 2000
EN 455-2 : 2009
EN 455-3 : 2006

START OF CE-MARKING : January 01,2005
PLACE,DATE OF ISSUE :

SIGNATURE :



NAME : KUAN EUI JIN
POSITION : QUALITY MANAGEMENT REPRESENTATIVE

INFORMATIONSKOP
Wird bei Änderung
nicht erfaßt.