TOP GLOVE GROUP OF COMPANIES

Tan Sri
OK to proceed
08/1

Memo

To : All Marketers, All Purchasing, All QA, TG Europe

From : RA Department

CC : Tan Sri Dr. Lim Wee Chai, Mr. Puon Tuck Seng, Pn. Noor 'Akilah, Mr. Eddy

Date : 29 December 2010

Re : New labeling requirement according to new Directive 2007/47/EC (amendment to the Medical Device Directive 93/42/EEC).

Please be informed that effective from 21 March 2010, according to new directive of 2007/47/EC (amendment Medical Device Directive (MDD) 93/42/EEC), the below new labeling must be shown on all artwork packaging material (both inner and carton) of medical gloves both in-house & private (OEM) brands to Europe markets as below:-

1. "Single Use" (to clarify the single use of medical devices for single patient).

   Examples of use of words or symbol for "Single Use"

   (i) • Single Use Only

   (ii) 

2. "European Authorized Representative (EAR)" statement must be explicitly stated. (For reference and to be contacted in terms of meeting the obligations by the Directive for all classes of devices).

   The options to place the EAR on the packaging material are as follows:

Option	**Brand**	**Labeling on the packaging material**		
		Current status of the labeling (apply to box & carton)	**Action on the packaging material**	**Note**
A	OEM	Only customer's full address but *without* TG's name and address appears on the packaging	Not require to put EAR	Management encourages customer to choose option A but customer must have his own CE mark registration. Marketers are required to ask customer to send their CE mark registration as record.

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Option	Brand	Labeling on the packaging material		
		Current status of the labeling (apply to box & carton)	**Action on the packaging material**	**Note**
B	OEM	Customer's full address with TG's name and address as manufacturer appears on the packaging	Requires to put EAR (Top Glove Europe address as above) in addition to the customer's address.	However, in some countries, where the customer needs to mention manufacturer's name and address on their labeling, then option B is to be selected.
C	OEM	Without customer's address and TG's address on the packaging	Compulsory to put EAR together with TG name and address as manufacturer.	For customer that do not have own CE mark registration to go for this option C
D	OBM	Must put EAR together with manufacturer's name and address (TG) on the packaging		

Note: OEM – Original Equipment Manufacturer/Customer's brand.
OBM – Own Brand Manufacturing/In-house's brand.

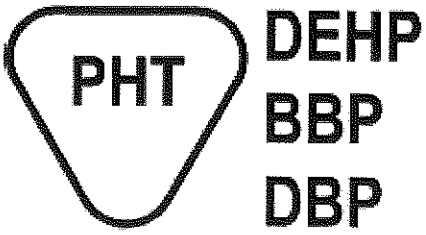
Examples of use of words or symbol for "European Authorized Representative (EAR)"

(i) EEC Representative:
Top Glove Europe GmbH, Germany.

(ii) 

Top Glove Europe GmbH, Germany

3. If **VINYL** gloves contain "phthalates" which is compounded using DEHP or DOP as plasticizer where they are under categories of carcinogenic, mutagenic or toxic to reproduction, then the packaging material must be labeled accordingly.
Examples of use of symbol for "contains or presence of phthalate": combination of DEHP, BBP and DBP (for phthalates under categories of carcinogenic, mutagenic or toxic to reproduction)



Note: The symbol is in draft standard, to be advice (TBA) once official commence.

Marketers are required to check all customers' artwork and to update customer on this new requirements.

Please comply to these new labeling requirements with immediate effect.

For further information, please refer to Mr. Eddy, Pn. Akilah or Mr. Puon Tuck Seng.

Please be guided accordingly.

Thank you.

Verified By: _____

Mr. Puon Tuck Seng

Senior Factory Manager

Approved by: _____

Mr. Lee Kim Meow

Managing Director

Checked By: _____

Mr. Eddy Rosyadie

QA Manager

Checked By: _____ 4/1/2011

Pn. Noor Akilah Saidin

Deputy General Manager (QA)

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