

DEKRA Certification UK Ltd

This form documents changes that are planned by the manufacturer. Please complete the 2 pages of this form. Based on the information supplied, DEKRA Certification Ltd will decide on the proposed change for further action(s).

NOTICE OF CHANGE

Manufacturer (please add name and address):	
--	--

Applicable Certificate number: Product group:	
--	--

Your change reference (internal manufacturer reference of change):	
--	--

Kind of change Please tick appropriate box			
Design Change	<input type="checkbox"/>	Extension of product range	<input type="checkbox"/>
Intended use	<input type="checkbox"/>	Supplier	<input type="checkbox"/>
Performance specifications	<input type="checkbox"/>	Production process	<input type="checkbox"/>
Major component	<input type="checkbox"/>	Production technology	<input type="checkbox"/>
Raw material	<input type="checkbox"/>	Production location	<input type="checkbox"/>
Label or IFU	<input type="checkbox"/>	Sterilization method/sterilizer	<input type="checkbox"/>
Product name	<input type="checkbox"/>	Documented Quality system	<input type="checkbox"/>
Packaging	<input type="checkbox"/>	Change of key personnel	<input type="checkbox"/>
Organization	<input type="checkbox"/>	Change in pathogen / marker	<input type="checkbox"/>
Preventive and/or corrective action(s) originating from post market surveillance	<input type="checkbox"/>	Other	<input type="checkbox"/>

--	--	--	--

DEKRA Certification UK Ltd

NOTICE OF CHANGE

Description of the change:	
Reason for the change:	
Planning documents related to the change: <i>For example ECO / quality plan / training plan etc.</i> <i>These documents shall also be sent with this form.</i>	
Documents impacted by change and new documents:	
Date when impacted and new documents can be submitted to DEKRA: <i>If already available, these documents shall also be sent with this form.</i>	
Name:	Function:
Date:	Signature: