

Takara Belmont Corporation
 2-1-1, Higashishinsaibashi,
 Chuo-ku, Osaka, 542-0083, Japan
 Phone : 81-6-6213-5945

EU DECLARATION OF CONFORMITY

We hereby declare that the bellowing statement is accurate and are exclusively responsible for the content.

Manufacturer's name:	Takara Belmont Corporation	
Business address:	2-1-1, Higashishinsaibashi, Chuo-ku, Osaka, 542-0083, Japan	
	Phone : 81-6-6213-5945	
	Fax : 81-6-6212-3680	
Product type:	DENTAL LIGHT	
Model name:	300LED DENTAL LIGHT	
Classification:	Type:	CLASS I
	Rule:	defined by the rule 13 of MDR ANNEX VIII
	Code:	12351
GMDN:	Term:	Light, dental, general-purpose
	Traceable document: EXPJ Production number list	
Applicable Product core code:	AL-3*	
EC Regulation/ Directives applied:	MDR (Medical Device Regulation):REGULATION (EU) 2017/745 based on Annex II & III	
	RoHS Directive:2011/65/EU based on category 8 of Annex I	
	Standards applied:	
Standards applied:	EN 1041:2008+A1:2013	EN 60601-1:2006/A1:2013
	EN ISO 9680:2014	EN 60601-1-2:2015
	EN ISO 13485:2016	EN 60601-1-6:2010/A1:2015
	EN ISO 14971:2012	EN 62304:2006/AC:2008
	EN ISO 15223-1:2016	EN 62366-1:2015
	EN 50581:2012	
Applied Common Specifications:	Not applicable	
SRN (Single Registration Number):	Not applicable	
UDI-DI:	Not applicable	
	number:	Not applicable
	Expiry date:	Not applicable
MDR certification:	NB number:	Not applicable

Representative in EU:
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Signature:

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Managing Director

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