#### **CE Marking for Medical Devices**

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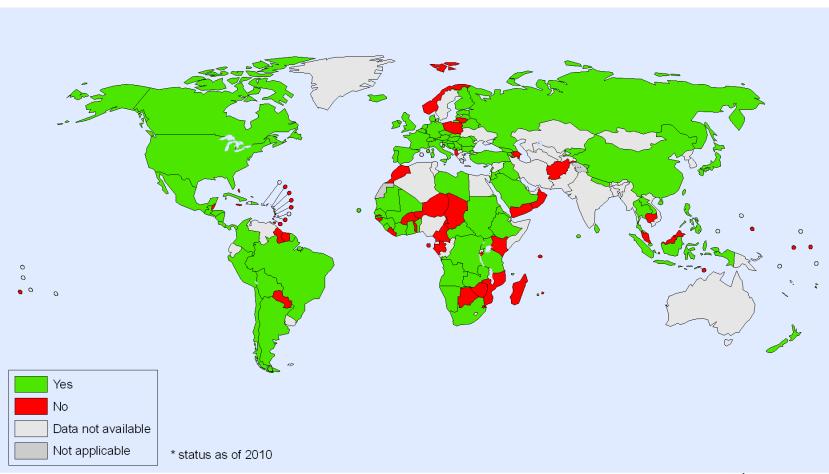
# Getting your medical device to market... **Evaluate** Design 12 Test Prototype Installation Validation Verification **Procedures** Copyright © 2012 BSI. All rights reserved.

# Getting your medical device to market...





#### National Regulatory Agency for Medical Devices\*



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# Medical Device Regulations in Europe

- Medical Devices Directive  $\rightarrow$  CE Marking
- Derogation into law by Member States
- 'Competent Authority'
- Notified Body





# CE marking in a single slide

- 1. Check Scope of Medical Device Directive
- 2. Determine "Device Class"
- 3. Select "Conformity Assessment Procedure"
- 4. Identify Applicable "Essential Requirements"
- 5. Assemble "Technical Documentation"
- 6. Apply Conformity Assessment Procedure
- 7. Complete "Declaration of Conformity"
- 8. Affix "CE Mark", Register with CA
- 9. Review and update, Post-Market Surveillance

(Article 9, Annex

(Article 1)

(Article 11)

(Article 3, Annex I)

IX)

(Annex II, III, VII)

(Annexes II-VII)

(Annexes II-VII)

(Article 17, Article 14)

(Annexes II, IV, V, VI, VII, VIII, X)

#### bsi.

# 1. Check Scope of Medical Devices Directive

- Is this a medical device?
- Are you the legal manufacturer?

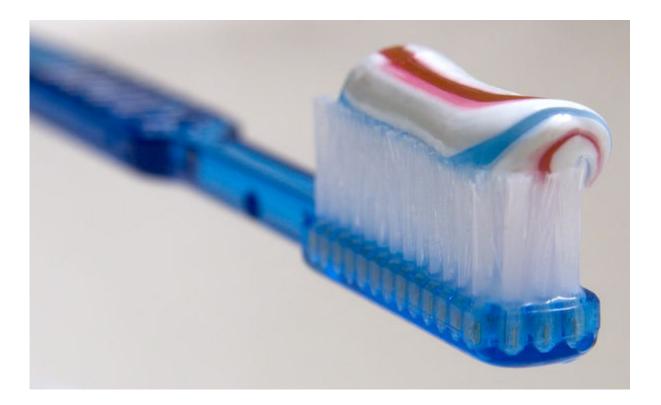
# Definition of Medical Device per the Directive...

			1		
	Article 1				
	Definitions, scope		of or compensation	vitro diagnostic those devices,	
For the purposes of	hall apply to medical devices and the this Directive, accessories shall b	be treated as	f the anatomy or of	by their manu- preservation of purpose of in	
sories shall hereinafte		initions shall is being used to with th	ded action in or on ogical or metabolic ion by such means;	vitro diagnostic their character- er to be used for	5/EEC;
apply:	s of this Directive, the following de		being a device is used together with with the use of the	ically made in	In deciding
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used specifically necessary for its to be used for hu	ourposes and te manufacturer if	r, control material, tem, whether used ifacturer to be used including blood and	ade out by any al qualifications	r);	
— diagnosis, pro disease,		ally for the purpose	ed to meet the r or any other d to be custom-	ls of human of placing on the exception	
			state, or	ins any device	are enception
	<ul> <li>— concerning a congenital</li> <li>— to determine the safety pients, or</li> </ul>		with potential reci-	actitioner when h 2.1 of Annex	to products
- to monitor therapeutic measures.				tion, any other	uman origin,
person who, by virtue of his professional qualifications, is authorized to carry out such investigation shall be accepted as					
manufactured utilizing animal tissue which is rendered					s a device is 1 non-viable or
<ul> <li>non-viable products derived from animal tissue.</li> </ul>					
4	Comminist © 20	12 DCI All vichte veee			

#### What is a Medical Device?



#### What is a Medical Device?





# What is a Medical Device?

'medical device' means any instrument, apparatus, appliance, software, material or other article... intended by the manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- ...(or of) an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

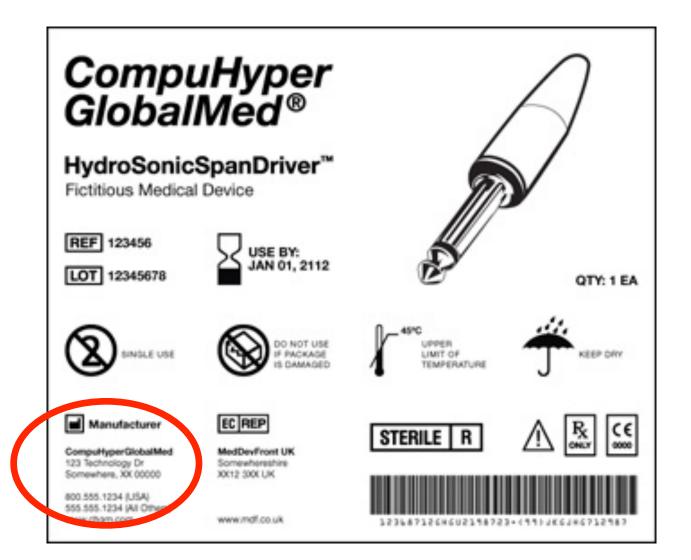
and which does not achieve its principle intended action ... by pharmacological, immunological or metabolic means..

# What is (or is not) a Medical Device?

Medical Devices Directives do not cover:

- Medicinal products
- Cosmetics
- Human blood derivatives
- Transplants or tissues of human origin
- Transplants or tissues of animal origin (unless non-viable)

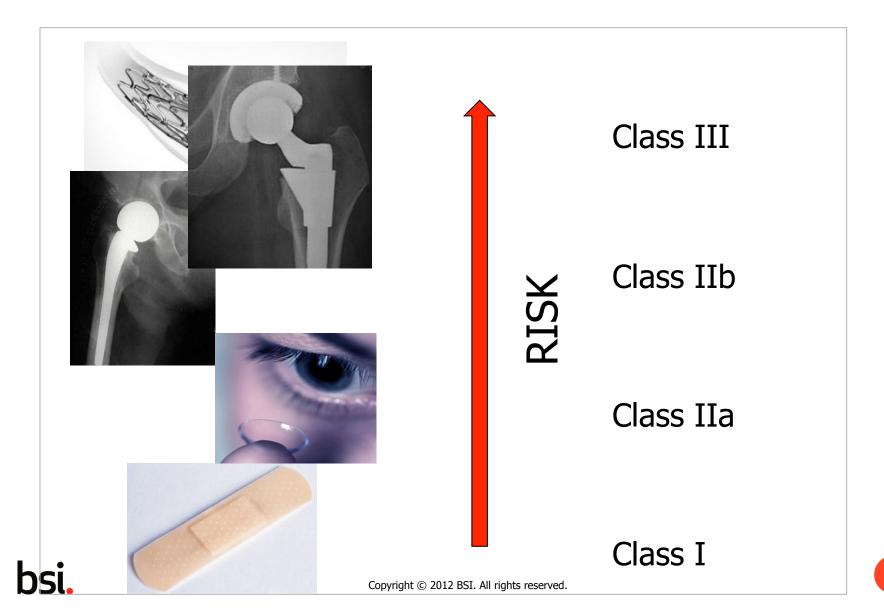
# Who is the legal manufacturer?



1. Check Scope of Medical Device Directive

# 2. Determine Device Class

#### Annex IX Classification Rules



- 1. Check Scope of Medical Device Directive
- 2. Determine Device Class

# 3. Select "Conformity Assessment Procedure"

# "Conformity Assessment Procedure" according to Risk

Notified Body: Full Quality Assurance and Design Examination for each product

Notified Body assessment of Quality Assurance: Design, Product or Production

Class III Class IIb RISK Class IIa Class I

Manufacturer Self Assessment

# "Conformity Assessment Procedure" – Class I

- Self-certification no Notified Body involvement
- Assemble technical documentation + register with Competent Authority



# "Conformity Assessment Procedure" – Class IIa

- Batch testing OR
- Production Quality Assurance OR
- Product Quality Assurance (final inspection and test) OR
- Full Quality Assurance (includes sample of technical documentation)







# "Conformity Assessment Procedure" – Class IIb

- Routes as for Class IIa devices + "Type Examination" OR
- Full Quality Assurance (includes sample of technical documentation)





# "Conformity Assessment Procedure" – Class III

- 'Type' Examination + Batch or Production QA OR
- Full Quality Assurance + Design Examination



- 1. Check Scope of Medical Device Directive
- 2. Determine Device Class
- 3. Select "Conformity Assessment Procedure"

## 4. Identify Applicable "Essential Requirements"

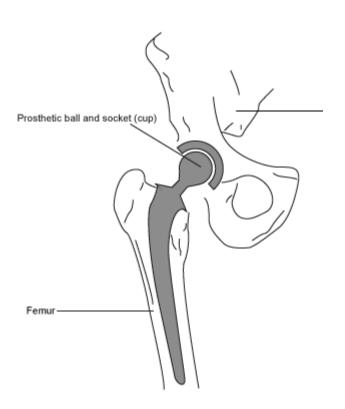
# **Essential Requirements (ER)** What are they?

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		L GINERAL REQUIREMENTS	as regards toxicity and,						
<b>V</b> M5			ed and biological tissue,		7				
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	pervided that	d health of users or, where applicable, other persons, any risks which may be associated with their intended	cal or modeling research	ity (i.e. the one involved					
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	This shall be	lade .	and packed in such a way	this information has an of the addition of the	L.				
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	same).		nul use or during routine	n, in accordings with f 27 June 1967 on the	oth state and non-statis	faily bacardose, visible and/	this destric shocks during nerned revided the devices are installed		
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		generally acknowledged man of the art	the intended use.	and to administer and/or	indon with other devices or ding the connection system		mathematical match a way as to mechanical risks connected with		
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		or reduce tikes as for an possible (theoremity safe design)	a medicinal product as	are casefied as card-		cal as fir as possible.	ctured in such a way as to reduce		nce and calibration needed to
	and constr	action)	C and which is liable to that of the device, the	of category 1 or 2, in 540/IEC, these devices	tured in such a way as to		arising from vibration generated brical progress and of the means	of the manufacture: For a view of their distribution	perfy and safely at all times;
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		in of the meldual risks due to any shorts mings of the measures adopted	agraph, the notified body	treatment of children or the manufacturer must		da la dim.	a string from the noise emitted, and of the means available to	be device and the contents	g specific investigations or
3.		nut ableve the performances intended by the manu-	substance as part of the intended purpose of the	f these substances with	frequencies environmental		unless the noise emitted is part	s,	
	that they are	e designed manufactured and packaged in such a way mimble for one or more of the functions referred to in	the competent authorities ocean Mediches Agency	nemens, in particular of nutrion and, within the	operators or variations in	ion must be designed and that when practicable, the	fecticity, gas or hydraulic and	1	ont of damage to the starile istalls of appropriate methods
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4	The characteri	storach performances reliand to in Sections 1, 2 and 3 abstrach, effected to such a derive that the clinical	of the incorporation		other devices normally used at given		way as to minimize all possible	aded by the word "LOT".	on the appropriate processes
	conditions and	adversely affected to such a degree that the clinical i using of the parints and, when applicable, of other	issuing its opinion, the into account the manu-	d in such a way as to the unintendinal increas	libration are not note bie (as	ad for diagnostic radiology a way as to achieve appro-	ding the parts or areas intended to	date by which the device	distriction, parkaging and, adjustion of the divice to be
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		ing normal conditions of usa	at, a human blood det-	ded to be used.	tured in such a way as to	al for the postic raliology	the partient by mercy appoint or	device is for single use. A	e intention that they be star- deaning and staribution must
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	fection.	the second	beneficitisk profile of the sinto the device. When	not allow easy handing to of the device by the	-	ted to or equipped with an	guannies the sality of the patient	de l'autors-made device";	t the device is for sindle use.
6.	Any under the	is side effect must constitute an acceptable risk when at the performance intended.	to account the manufac-		1		te of preventing and/or indicating	byedigations, the words	s and technical factors known
-	wagon again	a tem persona a los interneto.	lines of incomposition of by the notified hody.	minule that have been signed adapted to the	e designed and manufactured sourcey and sublity within	ability and performance of	ich could pose a danger.		a 13.1 po instructions for use
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			(9 03 No. L. 39, 15)	1 1990, p. 40. Directive as last access	delity Director 1910 35RC (DJ		the information mediad to use the	menta.	on sources, etc.;
			No.L. 207, 7-02.0			und in such a way as to	the device itself and/or on the an appropriate, on the sales	nut cottain he following	melicinal product or products igned to administer, including
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							(g) 4	the or table or the latest revision	or the instantion for use

# **Essential Requirements (ER)** What are they?

- Devices must be safe, effective, and fit for purpose
  - General: performance as intended, safe, state of the art, risks must outweigh benefits, durable over lifetime, packaging, shelf life
  - Clinical evaluation
  - Specific: biocompatibility testing, sterilisation validation, mechanical testing, software validation, electrical safety, compatibility with other devices, etc...
  - Reference to harmonised and other key standards
  - Warnings, labels, instructions

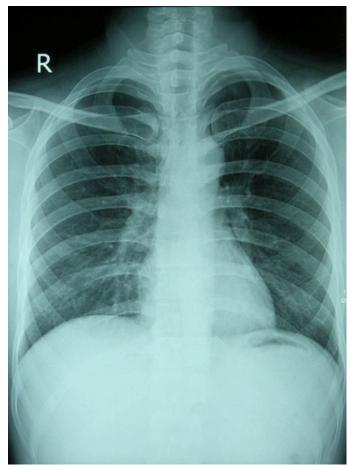
# Applicable Essential Requirements - examples



- Mechanical test data (fatigue, wear, surface finish, sphericity, etc)
   (ISO 21534, ISO 7206, ISO 14242, etc...)
- Biocompatibility (ISO 10993 series)
- Useability / ergonomics of instruments (EN 62366)
- Sterilisation (EN 556, etc)
- Packaging (ISO 11607 and related standards)
- Clinical Evaluation (ISO 14155)
- Labelling (EN 1041, EN 980)



# Applicable Essential Requirements - examples



- Electrical safety (EN 60601-2-44)
- Ionising radiation (EN 60601-1-3, EN 60601-2-8, EN 60601-2-38)
- Imaging resolution and accuracy (EN 62220-1)
- Usability / ergonomics (EN 62366)
- Clinical Evaluation (ISO 14155)
- Labelling (EN 1041, EN 980)

- 1. Check Scope of Medical Device Directive
- 2. Determine Device Class
- 3. Select "Conformity Assessment Procedure"
- 4. Identify Applicable "Essential Requirements"

# 5. Assemble "Technical Documentation"

# What is "Technical Documentation"?

- Device description and manufacturing process
- Risk evaluation
- Results of testing to demonstrate compliance to ERs (biological safety, sterilisation validation, packaging validation, mechanical testing, etc)
- Clinical evaluation
- Labelling and instructions
- Post-market surveillance plan

# Post Market Surveillance

- Application for assessments of quality systems (ie conformity routes) must include: "an undertaking by the manufacturer to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase,"
- Requirement for all medical devices, to ensure safety and performance are still comparable with state of the art

• Impact of clinical evaluation by design equivalence



#### Post Market Experience - example



- 1. Check Scope of Medical Device Directive
- 2. Determine Device Class
- 3. Select "Conformity Assessment Procedure"
- 4. Identify Applicable "Essential Requirements"
- 5. Assemble "Technical Documentation"

# 6. Apply Conformity Assessment Procedure

# **Conformity Assessment Procedure**

- Class I: Assemble technical documentation + register with Competent Authority
- Class IIa or IIb: Send product samples to NB for testing, or arrange appropriate quality system audits and technical documentation samples
- Class III: NB to audit Full Quality System and Design Examination of device



- 1. Check Scope of Medical Device Directive
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- 6. Apply Conformity Assessment Procedure

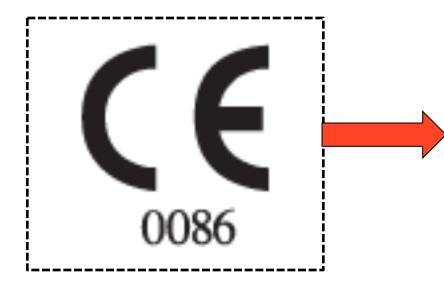
# 7. Complete "Declaration of Conformity"

## Example "Declaration of Conformity"

QuickLase Limited. 18 Dover Street, Canterbury CT1 3HD United Kingdom Tel: 0044 1227 80009 www.quicklase.com	<b>CE</b> 0473
Е	C Declaration of Conformicy Document Number: QWLASER_01
	ve address declare that the products detailed below are in complexed with /EEC as amended by 2007/47/EC.
Equipment description Make/Brand Models	QuickLase QWLASERX where X=3,5,8,10, other
MDD Classification Laser Classification Notified Body:	QWLASER10 Dual IIA Class IV Intertek AMTAC Certification Services Limited Davy Avenue Knowlhill Milton Keynes MK5 8NL, UK Tel, 0044 908 857 750
Certificate Number	941 CF trated by an assessment with respect to the essential require. onts set out
in timex I of Directive and by EN 60601-1:2006 M safety and essential J EN 60601-2-22:1990 Specification for dia, EN60601-1-2: 2007 EN60825-1:2007 Sa	y reference to the following harmonised standards
Canterbury, March 2010	
Fadi Nahab Sales Manager	

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# 8. Affix "CE Mark", Register with CA



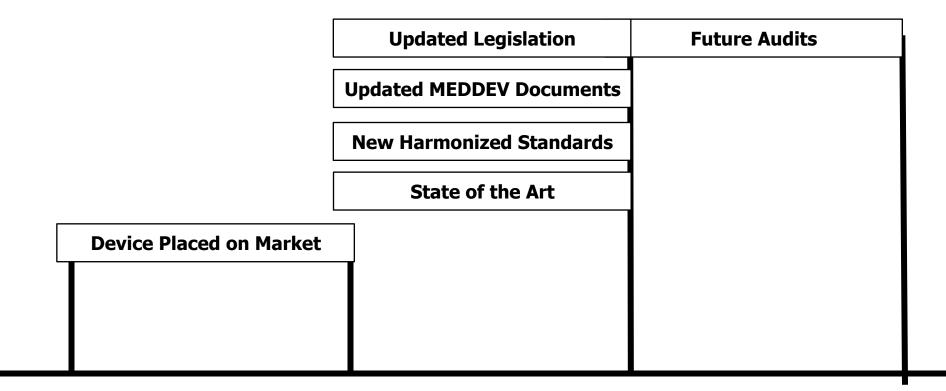
#### Article 14:

"Any manufacturer who, under his own name, places devices on the market .... shall inform the competent authorities of the Member State in which he has his registered place of business of the address of the registered place of business and the description of the devices concerned."

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#### 9. Review and update, Post-Market Surveillance

# Updating the Information:



## Feedback from manufacturers...

Dear Ms Smirthwaite,

We were extremely dismayed to hear your opinion that the requires a clinical trial.

The cost of clinical trials is prohibitive, and we are a small company and cannot possibly afford this.

Moreover, we secured venture capital on the basis that we would be able to market the device in Europe by Q3 2013. Without the revenue and clinical data generated by the European launch, we will be unable to gain market approval for these devices in the US...

# CE marking in a single slide

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(Article 1)	

(Article	9,	Annex	IX)
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(Article 11)

(Article 3, Annex I)

(Annex II, III, VII)

(Annexes II-VII)

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(Article 17, Article 14)

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# Any Questions?

