




Chaussée de Vilvorde, 156
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NOTIFIED BODY EC CERTIFICATE OF CONFORMITY		Certificate N° 12/CH/2762-0-REV 3 Page 1/5
In accordance with Appendix II of the Medical Devices Directive 93/42/EC & the latest amendment 2007/47/EC, excluding section 4		
Manufacturer	Name	Dr. Ihde Dental AG Simpladent GmbH oneway Suisse GmbH onewaybiomed GmbH Dr. Ihde Dental GmbH (*1)
	Address	Dorfplatz 11 CH-8737 Gommiswald Switzerland
<p>Scope:</p> <p>Development and production of dental, maxillo-facial and endodontic implants, suprastructures, accessories, drills, tools and instruments for implants, dental filling materials, materials for dental laboratory, rotary instruments, disinfectants for medical devices, dental sutures , single use sterile items.</p> <p>Production facilities and scopes: page 2/5</p> <p>Product classification: page 3/5 to 5/5</p>		
<p>This is to certify that the Quality Management System of the above mentioned manufacturer has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EC and conforms to the requirements for the equipment shown above. The approval is subject to the continued maintenance of the Quality System in accordance with the requirements of the above Directive, this shall be controlled by intermediate audits, inspections and surveys.</p>		
<p>The manufacturer is allowed to affix the "CE" mark followed with our notified body identification number 0029 to the approved equipment in the conditions described in the Directive.</p> <p style="text-align: center;">The approval is valid until 10/04/2017</p>		
Date : 07/06/2013	Name : Ch. Leplat	Position General Manager
Notified body identification number :	0029	Signature
Notified body stamp :	<p>APRAGAZ <i>Signature of Ch. Leplat</i></p> <p>Belgium Inspecting Authority</p> 	
Notified body reference :	P14340/001	



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In accordance with Appendix II of the Medical Devices Directive 93/42/EC & the latest amendment 2007/47/EC, excluding section 4		
Location	Scope of application	
Dr. Ihde Dental AG Dorfplatz 11 CH-8737 Gommiswald Switzerland Lindenstraße 68 CH-8738 Uetliburg Switzerland	Development and production of dental, maxillo-facial and endodontic implants, suprastructures, accessories, drills, tools and instruments for implants, dental filling materials, materials for dental laboratory, rotary instruments, disinfectants for medical devices, dental sutures , single use sterile items.	
Simpladent GmbH Dorfplatz 11 CH-8737 Gommiswald Switzerland		
oneway Suisse GmbH Dorfplatz 11 CH-8737 Gommiswald Switzerland		
onewaybiomed GmbH Dorfplatz 11 CH-8737 Gommiswald Switzerland		
(*1) Dr. Ihde Dental GmbH Erfurter Str. 19 DE-85386 Eching Germany		
Dentamechanik s.r.o. U Pily 581 CR-370 01 Ceske Budejovice Czech Republic	Production, cleaning and packaging of precision parts for implant systems, maintenance of medical devices	
Date : 07/06/2013	Name : Ch. Leplat	Position General Manager
Notified body identification number :	0029	Signature
Notified body stamp :		
Notified body reference :	P14340/001	



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Manufacturer	Name	Dr. Ihde Dental AG
	Address	Dorfplatz 11 CH-8737 Gommiswald Switzerland

Product	Technical file reference	Class
Dental implants, maxillo-facial implants, screws, abutments, tools, accessories and drills for dental implants and maxillo-facial implants"	31	IIa/IIb
Zirkonium for dental use	101	IIa
Dentamed E & B 1	202	IIa
Dentamed E & B 2	203	IIa
Ionomolar	204	IIa
Dentamed E & B SD 1	205	IIa
Ihdent TempBase	206	IIa
Ihdent TempBase Perfekt	207	IIa
Dentamed P&B	208	IIa
Dentamed E & B SD 2	209	IIa
Experdent APH	218	IIa
Dentamed Etching Gel	220	IIa
Glasionomer Cements	222	IIa
Priginal H	223	IIa
Triomolar	224	IIa
CemBase	229	IIa
Ihdent GIZ silver	232	IIa
Ihdent GIZ fil Typ II	233	IIa
Ihdent GIZ fil	234	IIa
Ihdent GIZ fil XN	235	IIa

Date : 07/06/2013 Name : Ch. Leplat Position **General Manager**

Notified body identification number : **0029**

Notified body stamp :

APRAGAZ
Belgium
Inspecting Authority

Notified body reference : **P14340/001**

Signature *Ch. Leplat*





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Manufacturer	Name	Dr. Ihde Dental AG
	Address	Dorfplatz 11 CH-8737 Gommiswald Switzerland

Product	Technical file reference	Class
Dentamed P&B II	239	IIa
Enamelite	241	IIa
Alloys for dental use	243	IIa
Ihdentalloy K	244	IIa
Ihdentalloy MG	245	IIa
TAK	246	IIa
Xellalloy K	247	IIa
Calciumhydroxid-Liner	248	IIa
Bonding systems for dental use	250	IIa
Dentamed P&B III	257	IIa
Maxit	260	IIa
Jet Bond II	261	IIa
Ceramolar Flow	262	IIa
Disinfectants for medical devices	270	IIa
Suture Materials	276	IIa
Ceramolar	277	IIa
Zahnfüll-Kunststoffe	278	IIa
Disinfectants for medical devices	280	IIb
Allfit Prov	284	IIa
Sprühdesinfektion	290	IIa
Desinfektions- und Reinigungstücher	291	IIb
Desinfektionstücher	293	IIa

Date : 07/06/2013	Name : Ch. Leplat	Position : General Manager
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Manufacturer	Name	Dr. Ihde Dental AG
	Address	Dorfplatz 11 CH-8737 Gommiswald Switzerland

Product	Technical file reference	Class
Instrumentendesinfektion	294	IIb
Bohrerdesinfektion	295	IIb
Surgotol/Surgitol	296	IIa
Schnelldesinfektion	297	IIa
Flächendesinfektion	299	IIa
Abformdesinfektion	300	IIa
Sprühdesinfektion	310	IIa
Desinfektionstücher	311	IIa
Bohrerdesinfektion	313	IIb
Instrumentendesinfektion	314	IIb
Flächendesinfektion	315	IIa
Abformdesinfektion	316	IIb
Single use sterile items	329	IIa
Chirurgische Einweg-Kittel	330	IIa
Sterile chirurgische Handschuhe	331	IIa
Surgical Tip	332	IIa
Ceramics for dental laboratory	333	IIa
Rotating Instruments for dental use	340	IIa

Date : 07/06/2013	Name : Ch. Leplat	Position General Manager
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