

Discus Dental LLC.

Declaration of Conformity

Manufacturer: Discus Dental, LLC.
12121 W. Bluff Creek Drive, Suite 100
Los Angeles, California 90094
USA

Authorized EC Representative Emergo Europe
Molenstraat 15
2513 BH, The Hague
The Netherlands

Design Facility: Discus Dental, LLC.
12121 W. Bluff Creek Drive, Suite 100
Los Angeles, California 90094
USA

Manufacturing Facility: Discus Dental, LLC.
1700A South Baker Avenue
Ontario, California 91761
USA

Product Categories: Tooth Whitening Products

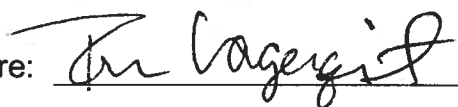
Product Ranges: See Attachment(s)

Classification: Class IIa based on Annex IX, Rule VI of Directive 93/42/EEC.

I, the undersigned, hereby declare that the Medical Devices specified above meet the provisions of Directive 93/42/EEC (MDD), including Amendment 2007/47/EEC, which applies to them, as transposed into the national laws of the EU member states.

This declaration is supported by the MDD, Annex V Approval 44 235 10 376535-001 issued by TÜV Nord on 2011-01-11, expiring on 2014-01-10, as well as the ISO 13485:2003 Quality Management System Certificate 908032 issued by Nemko-0470.

Place: Los Angeles, California USA Date: April 26 2012

Name: Ron Lagerquist Signature: 

Position Director of RA and QA Discus Dental, LLC.

ATTACHMENT TO THE DECLARATION OF CONFORMITY

Products: Tooth Whitening Products

Model Name	Model No.	Certificate No.(s)
Nite White ACP 10% Carbamide Peroxide	DBE2702 DBE2717 DBE2720 DBE2711 DBE2714	44 235 11 7811
Nite White ACP 16% Carbamide Peroxide	DBE2703 DBE2718 DBE2721 DBE2712 DBE2715	44 235 11 7811
Nite White ACP 22% Carbamide Peroxide	DBE2704 DBE2719 DBE2722 DBE2713 DBE2716	44 235 11 7811
Nite White ACP 10% Carbamide Peroxide with Fluoride	DBR2747 DBR2753 DBR2756 DBR2759 DBR2762	44 235 11 7811
Nite White ACP 16% Carbamide Peroxide with Fluoride	DBR2748 DBR2754 DBR2757 DBR2760 DBR2763	44 235 11 7811
Nite White ACP 22% Carbamide Peroxide with Fluoride	DBR2749 DBR2755 DBR2758 DBR2761 DBR2764	44 235 11 7811
Nite White Turbo ACP – 6% Hydrogen Peroxide	DBE2797 DBE2684	44 235 11 7811
Nite White Turbo ACP with Fluoride – 6% Hydrogen Peroxide	DBR2788	44 235 11 7811
Philips Zoom! Nite White 10% Carbamide Peroxide	ZNWE1000 ZNWE1001 ZNWE1002 ZNWE1003 ZNWE1004	44 235 11 7811
Philips Zoom! Nite White 10% Carbamide Peroxide with Fluoride	ZNWEF1000 ZNWEF1001 ZNWEF1002 ZNWEF1003 ZNWEF1004 ZNWEF1001RU ZNWEF1003RU ZNWEF1001SP ZNWEF1003SP	44 235 11 7811

Attachment to the Declaration of Conformity for Discus Dental LLC

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Model Name	Model No.	Certificate No.(s)
Philips Zoom! Nite White 16% Carbamide Peroxide	ZNWE1005 ZNWE1006 ZNWE1007 ZNWE1008 ZNWE1009	44 235 11 7811
Philips Zoom! Nite White 16% Carbamide Peroxide with Fluoride	ZNWEF1005 ZNWEF1006 ZNWEF1007 ZNWEF1008 ZNWEF1009 ZNWEF1006RU ZNWEF1008RU ZNWEF1006SP ZNWEF1008SP	44 235 11 7811
Philips Zoom! Nite White 22% Carbamide Peroxide	ZNWE1010 ZNWE1011 ZNWE1012 ZNWE1013 ZNWE1014	44 235 11 7811
Philips Zoom! Nite White 22% Carbamide Peroxide with Fluoride	ZNWEF1010 ZNWEF1011 ZNWEF1012 ZNWEF1013 ZNWEF1014 ZNWEF1011RU ZNWEF1013RU ZNWEF1011SP ZNWEF1013SP	44 235 11 7811
Day White ACP 9.5% Hydrogen Peroxide	DBE2689 DBE2693 DBE2695 DBE2699 DBE2701	44 235 11 7811
Day White ACP 7.5% Hydrogen Peroxide with Fluoride	DBR2726 DBR2732 DBR2735 DBR2738 DBR2741	44 235 11 7811
Day White ACP 9.5% Hydrogen Peroxide with Fluoride	DBR2727 DBR2733 DBR2736 DBR2739 DBR2742	44 235 11 7811
Day White ACP 38% Carbamide Peroxide	DBE2873 DBE2874 DBE2875	44 235 11 7811
Day White ACP 38% Carbamide Peroxide with Fluoride	DBR2877 DBR2878 DBR2879	44 235 11 7811

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Model Name	Model No.	Certificate No.(s)
Philips Zoom! Day White 9.5% Hydrogen Peroxide	ZDWE1000 ZDWE1001 ZDWE1002 ZDWE1003 ZDWE1004	44 235 11 7811
Philips Zoom! Day White 9.5% Hydrogen Peroxide with Fluoride	ZDWEF1000 ZDWEF1001 ZDWEF1002 ZDWEF1003 ZDWEF1004 ZDWEF1001RU ZDWEF1003RU ZDEEF1003SP	44 235 11 7811
Philips Zoom! Day White 14% Hydrogen Peroxide	ZDWE1005 ZDWE1006 ZDWE1007 ZDWE1008 ZDWE1009	44 235 11 7811
Philips Zoom! Day White 14% Hydrogen Peroxide with Fluoride	ZDWEF1005 ZDWEF1006 ZDWEF1007 ZDWEF1008 ZDWEF1009 ZDWEF1006RU ZDWEF1008RU	44 235 11 7811
Philips Zoom! Day White 6% Hydrogen Peroxide with Fluoride	ZDWEF1010 ZDWEF1011	44 235 11 7811
Relief ACP	PVE1602 PVE1609 PVE1620	44 235 11 7811
Zoom Weekender ACP – 6% Hydrogen Peroxide	ZM2566 ZM2567 ZM2568	44 235 11 7811
Zoom Weekender ACP – 6% Hydrogen Peroxide with Fluoride	ZM2521 ZM2522 ZM2523 ZM2566 ZM2568	44 235 11 7811
Zoom Chairside Gel 25%	22-3414	44 235 11 7811
Zoom! Chairside 16% Hydrogen Peroxide Gel and Kit	ZME2097 22-2862	44 235 11 7811
Zoom2 Chairside Gel 15%	22-2861	44 235 11 7811
Zoom2 Chairside 25% Hydrogen Peroxide Gel and Kit	ZME2529 ZME2531 ZME2534 ZME2535 22-2861 22-3435	44 235 11 7811

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Model Name	Model No.	Certificate No.(s)
Zoom Chairside Kit 25%	ZME2636 ZME2637 ZME2638 ZME2641 ZME2645 ZME2646	44 235 11 7811
Philips Zoom! Chairside Light-Activated Whitening Kit	ZME2666 ZME2665 ZME2665SP ZME2665R ZME2667 ZME2668 ZME2669 ZME2669R ZME2688 ZME2689 ZME2665RU ZME2668RU ZME2669RU	44 235 11 7811
Philips Zoom! Chairside Light- Activated 25% Hydrogen Peroxide Gel	22-3764 22-3788	44 235 11 7811
Zoom Whitening Pen	ZM2571	44 235 11 7811
Philips Zoom! Whitening Pen	ZME2676 ZME2675 ZME2675RU	44 235 11 7811
Dash	DSE1001	44 235 11 7811
BriteSmile 15% Hydrogen Peroxide Gel and Kit	BSE1008 22-3094	44 235 11 7811
BriteSmile 25% Hydrogen Peroxide Gel and Kit	BSE1018 22-3026	44 235 11 7811
BriteSmile To Go Pen	R0030 R0032	44 235 11 7811