

DECLARATION OF CONFORMITY (DoC-0700)

REVISION: 4

EFFECTIVE: February 2, 2023

AUTHOR:

Isaac Pineda

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Identification of the Legal Manufacturer:	Wolf X-Ray Corp. and Flow X-Ray Corp. dba Flow Dental 133 Wolf Road Battleboro, NC 27809, USA			
Identification of Authorized Representative:	Emergo Europe Westervoortsedijk 16 6827 AT Arnhem The Netherlands			
This Declaration of Conformity is issued under	er the sole responsibility of the manufacturer;			
Identification of the device(s) concerned:	X-Ray PPE including Aprons, Vests, Collars, Gonad Shields, and Gloves See full product list below			
Risk Classification:	Category III includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health relating to the following: (d) ionizing radiation			
We hereby declare that the above-mentioned	d devices comply with Regulation (EU) 2016/425;			
Relevant Harmonized Standards & Regulations	(EU) 2016/425 Module D (EU) 2016/425 Module B ISO 13485:2016 ISO 15223-1:2021 IEC 61331-1:2014 IEC 61331-3:2014			
Name and address of Notified Bodies:	SGS Fimko Oy, Notified Body 0598 Takomotie 8, Fl-00380, Helsinki, Finland t +358 9 696 361 www.sgs.com			
Applicable CE Certificate(s):	Wolf X-Ray Corp. and Flow X-Ray Corp. dba Flow Dental Regulation (EU) 2016/425, Module D Certificate# Fl19/81841462 Certified since 19 March 2019 Notified Body 0598 Wolf X-Ray Corp. and Flow X-Ray Corp. dba Flow Dental			



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Regulation (EU) 2016/425, EU type-examination Module B Certificate# 0598/PPE/22/3447 Issue 2 Certified since 14 October 2022 Notified Body 0598 Wolf X-Ray Corp. and Flow X-Ray Corp. dba Flow Dental Regulation (EU) 2016/425, EU type-examination Module B Certificate# 0598/PPE/22/3493 Issue 2 Certified since 14 October 2022 Notified Body 0598 Wolf X-Ray Corp. and Flow X-Ray Corp. dba Flow Dental Regulation (EU) 2016/425, EU type-examination Module B Certificate# 0598/PPE/22/3494 Issue 2 Certified since 14 October 2022 Notified Body 0598 Name: Isaac Pineda Signature: Title: Management Representative Identification of the person authorized to sign on behalf of Wolf X-Ray Corp Place of Issue: 133 Wolf Road Flow X-Ray dba Flow Dental: Battleboro NC 27809 Unites States of America February 2nd, 2023 Date:

Full Product List:

Wolf X-Ray

Stock Number XXXXX denotes product made with standard lead Stock Number XXXXXLW denotes product made with light weight lead

Stock Number XXXXXTC indicates product with Light weight lead & thyroid collar

Flow Dental

Stock Number XXXXX denotes product made with standard lead

All products listed below, with the exception of those with an * next to the name are available in the following colors; 12=Purple, 14=Teal, 16=Medium Blue, 18=Burgundy, 19=Gray, 20=Royal Blue, 22=Navy Blue, 23=Beige, 25=Black, 30=Tye Dye, 34=Paw Prints, 35=Red, 36=Hunter Green, 37= Shimmering Bronze, 38=Shimmering Green, 39=Shimmering Electric Blue, 40= Shimmering Navy Blue, 41=Shimmering Tan, 42=Antimicrobial



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Products are defined as (stock number) + (color number)

Example 62008-12 is a Conventional Apron. Standard lead, purple

Example 620	08-12 is a Conventional Apron, Standard lead, purple		
Company	Description		
Line			
Wolf	62008, 62018, 62019, 62020, 62021		
X-Ray	62008LW, 62018LW, 62019LW, 62020LW,	Conventional Apron	
	62021LW		
	63073, 63001, 63011, 63012, 63013		
	63073LW, 63001LW, 63011LW, 63012LW,	Coat Apron	
	63013LW		
	63073TC, 63001TC, 63011TC, 63012TC, 63013TC		
	65025, 65021, 65023, 65026, 65027		
	65025LW, 65021LW, 65023LW, 65026LW,		
	65027LW	Easy Wrap Apron	
	65025TC, 65021TC, 65023TC, 65026TC, 65027TC		
	66001, 66002, 66003		
	66001LW, 66002LW, 66003LW	Child-size Apron	
	66077, 66078, 66079, 66080, 66081, 66082, 66083,		
	66084		
	66077LW, 66078LW, 66079LW, 66080LW,		
	66081LW, 66082LW, 66083LW, 66084LW	Apron and Vest	
	66077TC, 66078TC, 66079TC, 66080TC, 66081TC,		
	66082TC, 66083TC, 66084TC		
*	67086, 67087, 67088, 67089, 67090	Special Procedure	
	67086LW, 67087LW, 67088LW, 67089LW,	Apron	
	67090LW		
	68091, 68093, 68095, 68096, 68097	Front Closing	
	68091LW, 68093LW, 68095LW, 68096LW,	Special Procedure	
	68097LW	Apron	
	68094LW, 68098LW, 68099LW, 68100LW,		
	68101LW	QR Quick Drop	
	69001, 69002, 69003	Child-size Front	
	69001LW, 69002LW, 69003LW	Closing Special	
		Procedure Apron	
	69095, 69096, 69097, 69098 Apro		
	75505-22	X-Ray Protective	
		"Rad Cap"*	
	75070	Soft Thyroid Collar	
	75060	Thyroid Collar	
	75080-22	Breast/Scoliosis	
		Stole*	
	75501-22	Gonad Shield Set*	
	75501-22	Gonad Shield Set*	



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	75500-23	Gonad Shield* Pro-Tek-To Pad Gloves*	
	75057		
	12419, 12422		
	End of Wolf X-Ray produ	ct line	
Flow Dental	75050	Adult Bib Apron without Collar	
	75051	Adult Bib Apron with	
	75053	Child Size Bib Apro with Attached Colla	
	75061	Adult Panoramic Apron	
	75062	Child Panoramic Apron	
	75090	CBCT Pano Cape with Collar	
	75091	CBCT Pano Cape without Collar	
	75056	Thyroid Collar	
	End of Flow Dental produ	ct line	

Revision History

Rev	Date	DCO#	Changes	Author
0	03/04/2020	N/A	Initial Issue	Marc Bader
1	05-05-2020	0041	Removed 'no lead' products from Full Product List Added Notified Body 0120, name, address, phone	Marc Bader
2	02-22-2022	N/A	Updated address and management representative	Isaac Pineda
3	06-23-2022	0090	Added Basic UDI-DI, added Gloves and CBCT Pano Cape to full product list, updated notified body and applicable CE certificates.	Isaac Pineda
4	02-02-2023	N/A	Updated EC Rep address, applicable certificates and removed redundant info.	Isaac Pineda