

# EC DECLARATION OF CONFORMITY

## MANUFACTURER

NAKANISHI INC.  
700 Shimohinata, Kanuma, Tochigi 322-8666, Japan

## AUTHORIZED EU REPRESENTATIVE

NSK EUROPE GmbH  
Elly-Beinhorn-Strasse 8, 65760 Eschborn, Germany

## MEDICAL DEVICE

General Product Group Name:  
Total Surgical System

Product Name: Primado2  
 Model: See No. 000089-083-001 011 Attachment 1  
 Order Code: See No. 000089-083-001 011 Attachment 1  
 Classification: Class IIa (Rule9)  
 Notified Body: TÜV Rheinland LGA Products GmbH  
 Tillystrasse 2, 90431 Nürnberg, Germany  
 Notified Body number: 0197



NAKANISHI INC. is exclusively responsible for the Declaration of Conformity.  
 The serial number applied to this product is managed by the "Shipping history data".  
 This Declaration of Conformity is valid for a definite number of manufactured products.

The undersigned hereby declares that the medical device, as specified above, conforms with the essential requirements listed in Annex I of EC Directive 93/42/EEC.  
 The Declaration of Conformity is based on the EC Directive 93/42/EEC Annex II, excluding Section 4. The Declaration of Conformity is issued under the supervision of TÜV Rheinland LGA Products GmbH, approving the conformity of Annex II Section 3 requirements, with reference to articles 1 and 3 of directive 93/42/EEC.

EC Certificate Registration No.: HD 60148508 0001  
 This Declaration of Conformity is valid until 2024-05-26.

And, this Declaration of Conformity includes the EC Directive 2006/42/EC.

Tochigi, Japan: 2021-01-19  
 Date

Masaaki Kikuchi,  
 Management Representative

**NAKANISHI INC.**

Product Name: Primado2

Components:

No.	Name		Model No. Order Code	
1	Control Unit	Primado2 Control Unit for 120V	P200-CU-120	
		Primado2 Control Unit for 230V	P200-CU-230	
2	Foot Control	Primado2 Single Foot Control	FC-73	
		Primado2 Multi Foot Control	FC-74	
3	Motor	Primado2 High Torque Motor	P200-HMH	
		Primado2 High Torque Motor/HS	P200-HMH-HS	
		Primado2 Slim Motor Short	P200-SMH-S	
		Primado2 Slim Motor	P200-SMH	
		Primado2 Slim Motor/HS	P200-SMH-HS	
		Primado2 Micro Bone Saw Motor	P200-BMH	
		Primado2 Micro Bone Saw Motor/HS	P200-BMH-HS	
4	Wire Pin Driver	Primado2 Wire Pin Driver	P200-WPD	
5	Bone Saw Handpiece	Primado2 Rec. Handpiece	P200-REC-S	
		Primado2 Rec. Handpiece/HS	P200-REC-S-HS	
		Primado2 Sag. Handpiece	P200-SAG-S	
		Primado2 Sag. Handpiece/HS	P200-SAG-S-HS	
		Primado2 Osc. Handpiece	P200-OSC-S	
		Primado2 Osc. Handpiece/HS	P200-OSC-S-HS	
6	Attachment	Bone Saw Attachment	Primado2 Rec. Attachment	P200-REC
			Primado2 Sag. Attachment	P200-SAG
			Primado2 Osc. Attachment	P200-OSC
	Attachment	Perforator Attachment	Perforator Handpiece200	P200-PER
			Perforator Handpiece	PD-PER
	Attachment	Slim Handpiece 200	Slim Handpiece200 L	P200-1A135
			Slim Handpiece200 EL	P200-1A155
			Slim Handpiece200 SL	P200-1A175
			Slim Handpiece200 EL/Curved	P200-1A155-C
			Slim Handpiece200 SL/Curved	P200-1A175-C
	Attachment	Primado Slim Attachment	Short Slim Handpiece	PD-1A75
			Middle Slim Handpiece	PD-1A95
			Long Slim Handpiece	PD-1A135
			Extra Long Slim Handpiece	PD-1A155
			Super Long Slim Handpiece	PD-1A175
			Extra Long Slim Handpieces with a curvature of 10°	PD-1A155-10
	Attachment	Super Slim Handpiece 200	Super Long Slim Handpieces with a curvature of 10°	PD-1A175-10
			Super Slim Handpiece200 L	P200-RA135
			Super Slim Handpiece200 EL	P200-RA155
			Super Slim Handpiece200 SPL	P200-RA330
	Attachment	Primado Super Slim Attachment	Super Slim Handpiece200 SPL/L	P200-RA330-L
			Medium Super Slim Handpiece	PD-RA95
			Long Super Slim Handpiece	PD-RA135
			Extra Long Super Slim Handpiece	PD-RA155
			Special Long Super Slim Handpiece	PD-RA330
			Special Long Super Slim Handpiece	PD-RA330-L
			Special Long Super Slim Handpiece	PD-RA330-L

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Product Name: Primado2

## Components:

No.	Name	Model No. Order Code	
	Standard Handpiece 200	Std. Angled Handpiece200 MS	P200-2AMS
		Std. Angled Handpiece200 ES	P200-2AES
		Std. Angled Handpiece200 S	P200-2AS
		Std. Angled Handpiece200 M	P200-2AM
		Std. Angled Handpiece200 L	P200-2AL
		Std. Straight Handpiece200 MS	P200-2SMS
		Std. Straight Handpiece200 ES	P200-2SES
		Std. Straight Handpiece200 S	P200-2SS
		Std. Straight Handpiece200 M	P200-2SM
		Std. Straight Handpiece200 L	P200-2SL
	Primado Standard Attachment	Extra Short Standard Angle Handpiece	PD-2AES
		Short Standard Angle Handpiece	PD-2AS
		Medium Standard Angle Handpiece	PD-2AM
		Long Standard Angle Handpiece	PD-2AL
		Extra Short Standard Straight Handpiece	PD-2SES
		Short Standard Straight Handpiece	PD-2SS
		Medium Standard Straight Handpiece	PD-2SM
	Long Standard Straight Handpiece	PD-2SL	
	Craniotome Handpiece 200	Craniotome Handpiece200	P200-CRA
		Pediatric Duraguard200	P200-CRD-P
		Medium Duraguard200	P200-CRD-M
		Long Duraguard200	P200-CRD-L
		Rotatable Duraguard200 P	P200-RCRD-P
		Rotatable Duraguard200 M	P200-RCRD-M
	Primado Craniotome Handpiece	Craniotome Handpiece	PD-CRA
		Pediatric Duraguard	PD-CRD-P
		Medium Duraguard	PD-CRD-M
		Long Duraguard	PD-CRD-L
	Drill Handpiece 200	Straight Drill Handpiece200	P200-2SD
	Primado Drill Attachment	Straight Drill Handpiece	PD-2SD
		Angled Drill Handpiece	PD-2AD
		Straight Drill Handpiece M	PD-2SDM
		Angled Drill Handpiece M	PD-2ADM
	High Speed Handpiece 200	High Speed Handpiece200 S	P200-3GAS
		High Speed Handpiece200 M	P200-3GAM
		High Speed Handpiece200 L	P200-3GAL
	Primado High Speed Attachment	Short High Speed Handpiece	PD-3GAS
		Medium High Speed Handpiece	PD-3GAM
		Long High Speed Handpiece	PD-3GAL
	Primado Contra Angle Attachment	Contra Angle Handpiece 16:1 Reduction	PD-CA-16
		Contra Angle Handpiece 64:1 Reduction	PD-CA-64
		Contra Angle Handpiece 256:1 Reduction	PD-CA-256

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Components:

No.	Name	Model No. Order Code	
	Primado Wire Pin Driver Attachment	Primado Wire Collet	PD-DA-W
		Primado Pin Collet	PD-DA-P
		Jacobs Keyed Drill Chuck	PD-DA-J4
		Jacobs Keyed Drill Chuck	PD-DA-J6
		AO Drill Chuck	PD-DA-A
		Keyless Drill Chuck	PD-DA-K
		Hudson Reamer	PD-RA-H
		AO Reamer	PD-RA-A
		Trinkle Reamer	PD-RA-T
		Hudson Modified Trinkle Reamer	PD-RA-M
		Reciprocating Saw Attachment	PD-SA-R
		Sagittal Saw Attachment	PD-SA-S
		Contra Angle Handpiece 200	Contra Angle Handpiece200 4:1
	Metal Cutting Handpiece 200	Metal Cutting Handpiece200	P200-3MC
	Slim Handpiece 300	Slim Attachment Hub/Angled	P300-1AHA
		Slim Attachment Hub/Straight	P300-1AHS
		Slim Tube 110	P300-1T110
		Slim Tube 110/C	P300-1T110-C
		Slim Tube 110/PB	P300-1T110-PB
		Slim Tube 130	P300-1T130
		Slim Tube 130/C	P300-1T130-C
		Slim Tube 130/PB	P300-1T130-PB
		Slim Tube 170	P300-1T170
		Slim Tube 240	P300-1T240
	Standard Handpiece 300	STD Attachment 10/Angled	P300-2A10
		STD Attachment 20/Angled	P300-2A20
		STD Attachment 40/Angled	P300-2A40
		STD Attachment 60/Angled	P300-2A60
		STD Attachment 80/Angled	P300-2A80
		STD Attachment 10/Straight	P300-2S10
		STD Attachment 20/Straight	P300-2S20
		STD Attachment 40/Straight	P300-2S40
		STD Attachment 60/Straight	P300-2S60
STD Attachment 80/Straight		P300-2S80	



Product Name: Primado2

Accessories:

No.	Name	Model No. Order Code	
1	Accessories	Irrigation Nozzle for Bone Saw	P200-IN-BS
		Irrigation Nozzle for 1A155	P200-IN-1A155
		Irrigation Nozzle for 1A175	P200-IN-1A175
		Irrigation Nozzle (Short)	PD-IN-3S
		Irrigation Nozzle (Medium)	PD-IN-3M
		Irrigation Nozzle (Long)	PD-IN-3L
		Irrigation Nozzle (Extra Short)	PD-IN-2ES
		Irrigation Nozzle (Short)	PD-IN-2S
		Irrigation Nozzle (Medium)	PD-IN-2M
		Irrigation Nozzle (Long)	PD-IN-2L
		Irrigation Nozzle for Drill Handpiece	PD-IN-D
		Adaptor	PD-OSC-A
		Slim Tube Hood	P300-1T-H
		Slim Tube Beak	P300-1T-B
		STD Attachment Beak	P300-2-B

LIETUVOS RESPUBLIKA  
Uždaroji  
akcinė bendrovė  
PRINCIPAL MED TL  
Administratore-vadybininkė  
Aušra Šalamonė  
KAUNO MIESTAS  
2022-04-14

NAKANISHI INC.

# Technical Document and Change History Control Form

技術文書・変更履歴管理票

Control number 管理番号	000089-083-001	Document name 文書種類名	EC DECLARATION OF CONFORMITY			
Rev. 改定	Site 箇所	Target item 対象項目	Content of change / Reason for change 変更内容 / 変更理由	Approved by 承認	Verified by 検証	Prepared by 作成
006	×7	Model	参照する別紙のリビジョンアップ	鈴木(亘) 2017.7.27	守屋 2017.7.27	佐土原 2017.7.27
		No.000089-083-001 Attachment 1	新製品の追加及び、表記ラベルとの整合が取れていないたつか製品名を修正			
007	-	フォーム改訂	フォーム改訂によるリビジョンアップ	鈴木(亘) 2018.3.30	守屋 2018.3.29	國澤 2018.3.29
		No.000089-083-001 Attachment 1	Modelの欄にOrder Codeを追加			
008	×1	EC Certificate Registration No.	変更前:HD 60118708 0001 変更後:HD 60144337 0001	鈴木(亘) 2019.12.20	鈴木(亘) 2019.12.20	手塚 2019.12.20
009	×5	No.000089-083-001 Attachment 1	新製品(P300)の追加 変更部管理方法変更(***) → (009) )	鈴木(亘) 20-01-28	鈴木(亘) 20-01-28	手塚 20-01-28
010	-	改版	①EC Certificate Registration No.更新 HD 60144337 0001 → HD 60148508 0001 ②EC-DOC有効期限更新 2022-05-08 → 2024-05-26 ③更新に伴う帳票改版	川久保 2020.11.24	最上 2020.11.24	竹原 2020/11/23
		Attachment 1 Page 4/4	変更履歴削除/当該履歴票で管理する。			
		技術文書・変更履歴管理票	文書種類名をFD-204と合わせる。 EC適合宣言書 → EC DECLARATION OF CONFORMITY			
011		Attachment 1 Page 1	新製品のP200-SMH-Sを追加			