

# 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:  
Dental abrasive powder

Product Name: FLASH Pearl  
Model: See No. 06043-12-21-02 006 Attachment  
Order Code: See No. 06043-12-21-02 006 Attachment  
Classification: Class IIa (Rule5)  
Notified Body: TÜV Rheinland LGA Products GmbH  
Tillystrasse 2, 90431 Nürnberg, Germany  
Notified Body number: 0197

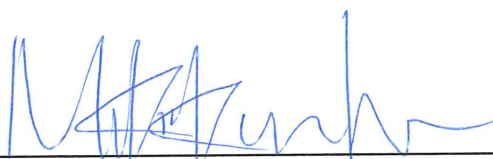
NAKANISHI INC. is exclusively responsible for the Declaration of Conformity.  
The lot number applied to this product is managed by the "Product Procedure Sheet".  
This Declaration of Conformity is valid for a definite number of manufactured products.

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.

Tochigi, Japan: 2020-11-19  
Date

  
Masaaki Kikuchi,  
General Manager Quality Assurance Department

No.	Model	Type	Order Code
1	PMN-PTL	FLASH pearl 100 pack	Y900693
2		FLASH PEARL (BOTTLE/4)	Y900698