

## DECLARATION OF CONFORMITY

Ultradent Products, Inc. has evaluated the following product by using the Conformity Assessment Procedure of Annex II of the Medical Device Directive 93/42/EEC, as amended by 2007/47/EEC:

### ViscoStat Clear

and confirms in sole responsibility that the product is compliant with the Essential Requirements of Annex I of the Medical Device Directive 93/42/EEC. Technical documentation is located in the Regulatory Affairs Department.

This product system is classified as Class IIa medical device according to the Medical Device Directive 93/42/EEC, Annex IX, Section III Classification 1.4, Rule 4

**UMDNS Code:** 17944, Hemostatic Media

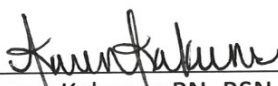
**GMDN Code:** 46423, Gingival retraction solution

**EC Representative:**

Ultradent Products GmbH  
Am Westhover Berg 30  
51149 Cologne  
Germany

**Notified Body:**

TÜV Nord Cert GmbH  
Unternehmensgruppe TÜV Nord  
Langemarckstraße 20  
45141 Essen, Germany  
ID No. 0044

  
\_\_\_\_\_  
Karen Kakunēs RN, BSN  
Regulatory Affairs Management

02 Dec 2020  
\_\_\_\_\_  
Date

State of Utah  
County of Salt Lake

Subscribed and sworn to before me on this 2 day of December 2020

By Karen Kakunēs  
\_\_\_\_\_

  
\_\_\_\_\_  
Notary Public



This document is in force as long as the following EC certificates are valid:

EC Certificate 44 232 090234 valid through 26 May 2024