

Date: 17.08.2023

## Declaration of validity of Annex I of the EC certificate Re.No.44 235 202395

The certificate Reg. No. 44 235 202395 applies to the following class IIa products:

**Table 1:**

Name of the product category	Name of the individual type	Nomenclature code <sup>1</sup>	Product
Dental products	Restorative material, dental	16-188	optiprint clara optimill memosplint optimill memosplint version S optiprint lumina optiprint laviva
	Composite restorative material, dental, thermosetting	16-726	dentona flexisplint dentona vivatemp

We hereby declare, on our sole responsibility, that the above-mentioned products comply with all applicable Essential Safety and Performance Requirements of Regulation (EU) 2017/745 and are manufactured in accordance with the Technical Documentation set out in Annexes II and III of this Regulation.

dentona AG has a comprehensive quality management system in accordance with Annex IX, Chapter I, Article 10 and Article 120 of the above-mentioned regulation and in accordance with EN ISO 13485:2016+ AC:2018 + A11:2021, which is subject to annual surveillance by the Notified Body EKAPTY, Reg.No. 301001927, 29/09/2022.

**Declaration of the status of a formal application, a contract and the corresponding monitoring under Regulation (EU) 2023/607 amending Regulation (EU) 2017/745 as regards the transitional provisions for the above-mentioned medical devices.**

This letter confirms that dentona AG, SRN: DE-MF-000005550, has submitted a formal application in accordance with section 4.3, first subparagraph of Annex VII of the MDR to TÜV NORD CERT GmbH, a Notified Body (NB) under Regulation (EU) 2017/745 (MDR) with the number NB 0044 and the registration number BS-MDR-095.21.01 on NANDO.

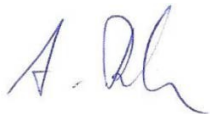
The application was accepted on 17/08/2023.

By accepting the application, the products listed in the table continue to be covered by certificate no. 44 235 202395 in accordance with Directive 93/42/EEC (MDD) and can be placed on the market as legacy devices until 26 September 2024.

Yours sincerely

Signature:

Date: 17/08/2023



Andreas Förster (Head of RA and PRRC dentona AG)