EU DECLARATION OF CONFORMITY

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5. APRIL 2017

Manufacturers Name:

Dentaco AS

Manufacturers Address:

Unnelandsveien 258, 5268 Haukeland, Norway

SRN

NO-MF-000007293

Basic UDI-DI

Eudamed - Autumn 2021

Name of Device

1. Barman's Anatomical Wedges

2. Barman's Easy Grip Wedges

Trademark

Barman's Anatomical Wedges

Model Name :

Barman's Anatomical Wedges Small

Product code: 7032573 040308

Catalog no.: 211

:

Barman's Anatomical Wedges Large

Product code: 7032573 040407

Catalog no: 221

Barman's Anatomical Wedges Mix

Catalog no: 201

Product code: 7032573 040209

Barman's Easy Grip Wedges

Product code: 7032573 040100

Catalog no: 231

Classification with rule number:

Class I, Annex VIII . Chapter III, Kap. 5. Invasive Devices

5.1 Rule 5

- Barman's Anatomical Wedges are «intended for transient use»

Conformity assesment route:

As per chapter V, section 2, article 52- Conformity assessment procedures clause number 7 states technical documentation related to class I devices as set out in Annexes II & III of Eu MDR 2017/745.

The declaration of conformity is issued under the sole responsibility of Dentaco AS in compliance to Article 19 og EU MDR 2017/745. We hereby declare that the medical device specified above meet the provision of the Annex IV of Regulation Eu MDR 2017/745 for medical devices.

Signature:

Place and date of issue:

Haukeland, 14. mai 2021

Merete Barman /CEO

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