

EU DECLARATION OF CONFORMITY

We,

MEDICOM Healthcare BV,
Parallelweg 80-A, 3931 MT Woudenberg, The Netherlands
SRN (Single Registration Number) : NL-MF-000007490

Declare that the declaration of conformity is issued under our sole responsibility and relates to the following products:

Basic UDI-DI: 87202499DECO01G5

REF number	Dimension	Weight g/ m ²	Product Trade Name
4551-300	8mm  x 38 mm	300	Medicom Dental Cotton Rolls, size 1
4552-300	10mm  x 38 mm	300	Medicom Dental Cotton Rolls, size 2
4553-300	12mm  x 38 mm	300	Medicom Dental Cotton Rolls, size 3
4553-400	14mm  x 38 mm	300	Medicom Dental Cotton Rolls, size 4
4551-1M	8mm  x 38 mm	430	Medicom Dental Cotton Rolls, size 1
4552-1M	10mm  x 38 mm	430	Medicom Dental Cotton Rolls, size 2
4553-1M	12mm  x 38 mm	430	Medicom Dental Cotton Rolls, size 3
4554-1M	14mm  x 38 mm	430	Medicom Dental Cotton Rolls, size 4
4554	10mm  x 38 mm	430	Medicom Dental Cotton Rolls, size 1

Product group: Cotton Rolls

Intended use: Absorbing of body and treatment process fluids for providing a dry treatment field for the dentist/ user.

Classification

The products are classified as Medical Devices according to definition of the MDR 2017/745.
They are class I products according to Annex VIII, rule 5 of the MDR 2017/745. No other rule is applicable

The devices covered by this declaration comply with the Regulation (EU) 2017/745 on Medical Devices.

The following harmonised standards and technical specifications have been applied: EN 14079

Conformity assessment procedure:

The products are subjected to the procedures set out in Annex I, Annex II and Annex III of Regulation (EU) 2017/745.
Furthermore we declare and assure, that the devices covered by this declaration comply with other relevant Union legislation providing for the issuance of an EU declaration of conformity, if applicable.

Name: Joachim Siegler

Place of issue: Leverkusen

Function: General Manager

Date of issue: 15.02.2023

Signature:



MEDICOM Healthcare BV

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