

EU declaration of conformity

We, the company

Dr. Jean Bausch GmbH & Co. KG
Oskar-Schindler-Straße 4
50769 Cologne
Germany

declare as manufacturer, SRN: DE-MF-000005577 in sole responsibility, that the products listed from page 2 onwards of the

Product group: 1.0 Progressively Coloring Articulating Papers
Basic UDI-DI: ++E2101x0xPaperx100x20085

meet the applicable requirements of Regulation (EU) 2017/745 on medical devices and the subsequent regulations and standards:

Regulation (EU) 2017/745
EN 10993-1:2020
EN 14971:2019
EN 62366:2015 + AC:2015 + A1:2020

The technical documentation proving compliance with the requirements of the above-mentioned regulations and standards is documented in the Development File and Medical Devices File parts of the technical file and is available to the National Competent Authorities.

This declaration of conformity is valid from: 2021-10-25.



Signed by: André Bausch
Authority: General Manager of Dr. Jean Bausch GmbH & Co. KG

Date of signature: 2021-10-25
Place of signature: Cologne - Germany

REF	UDI-DI	Product / Package	Content	Color	Version / LOT/SN (from ... to)	Classification, acc. to Annex VIII Rule(s) Class		Conformity assessment procedure, acc. to (EU) 2017/745
BK 01	+E210BK0104	Paper 200 microns, Plastic dispenser	300 strips	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 1001	+E210BK100105	Paper 200 microns, Refill-Box	300 strips	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 101	+E210BK10105	Paper 200 microns, Box with strips	50 strips	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 02	+E210BK0205	Paper 200 microns, Plastic dispenser	300 strips	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 1002	+E210BK100206	Paper 200 microns, Refill-Box	300 strips	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 102	+E210BK10206	Paper 200 microns, Box with strips	50 strips	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 03	+E210BK0306	Paper 200 microns, Horseshoe-Shape	50 sheets	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 04	+E210BK0407	Paper 200 microns, Horseshoe-Shape	50 sheets	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 05	+E210BK0508	Paper 200 microns, Booklets	300 strips	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 51	+E210BK5109	Paper 100 microns, Plastic dispenser	300 strips	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 52	+E210BK520A	Paper 100 microns, Plastic dispenser	300 strips	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 53	+E210BK530B	Paper 100 microns, Horseshoe-Shape	50 sheets	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 54	+E210BK540C	Paper 100 microns, Horseshoe-Shape	50 sheets	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 57	+E210BK570F	Paper 100 microns, Box with strips	50 strips	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 58	+E210BK580G	Paper 100 microns, Box with strips	50 strips	red	86001 ... 95099	5	I	Art. 19, Annexes II & III