

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: 1.4 Arti-Check® Articulating Papers
Basic UDI-DI: ++E2101x4xArtiCheckx404J

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

Form EU declaration of conformity (Doc)

REF	UDI-DI	Product / Package	Content	Color	Version / LOT/SN (from ... to)	Classification, acc. to Annex VIII		Conformity assessment procedure, acc. to (EU) 2017/745
						Rule(s)	Class	
BK 09	+E210BK090C	Paper 40 microns, Box with booklets	200 strips	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 10	+E210BK1004	Paper 40 microns, Box with booklets	200 strips	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 11	+E210BK1105	Paper 40 microns, Box with sheets 100 x 70 mm	100 sheets	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 12	+E210BK1206	Paper 40 microns, Box with sheets 100 x 70 mm	100 sheets	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 13	+E210BK1307	Paper 40 microns, Roll 16 mm wide, in dispenser	15 m	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 1013	+E210BK101308	Paper 40 microns, Roll 16 mm, Refill-Box	15 m	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 14	+E210BK1408	Paper 40 microns, Roll 16 mm wide, in dispenser	15 m	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 1014	+E210BK101409	Paper 40 microns, Roll 16 mm, Refill-Box	15 m	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 15	+E210BK1509	Paper 40 microns, Roll 22 mm wide, in dispenser	10 m	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 1015	+E210BK10150A	Paper 40 microns, Roll 22 mm, Refill-Box	10 m	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 16	+E210BK160A	Paper 40 microns, Roll 22 mm wide, in dispenser	10 m	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 1016	+E210BK10160B	Paper 40 microns, Roll 22 mm, Refill-Box	10 m	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 17	+E210BK170B	Paper 40 microns, Horseshoe-Shape	150 sheets	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 18	+E210BK180C	Paper 40 microns, Horseshoe-Shape	150 sheets	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 61	+E210BK610A	Paper 40 microns, Box with strips	200 strips	blue	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 62	+E210BK620B	Paper 40 microns, Box with strips	200 strips	red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 63	+E210BK630C	Paper 40 microns, Box with strips	200 strips	blue/red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 80	+E210BK800B	Paper 40 microns, Box with booklets	200 strips	blue/red	86001 ... 95099	5	I	Art. 19, Annexes II & III
BK 81	+E210BK810C	Paper 40 microns, Horseshoe-Shape	150 sheets	blue/red	86001 ... 95099	5	I	Art. 19, Annexes II & III