

EU Declaration of Conformity

to REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE
COUNCIL of 5 April 2017 on in vitro diagnostic medical devices

Manufacturer: Greiner Bio-One GmbH
Bad Haller Straße 32
4550 Kremsmünster
Austria

SRN: AT-MF-000024608

Production Greiner Bio-One GmbH
Location: Bad Haller Straße 32
4550 Kremsmünster
Austria

Product / MiniCollect® K3E K3EDTA TUBE
Product Group: (for details please refer to page 2)

BASIC-UDI-DI (GMN): 912001757G00000449T

Classification: Class A according to Regulation (EU) 2017/746 of the european parliament and of
the council of 5 April 2017 on in vitro diagnostic medical devices, Annex VIII
Classification Rules - Rule 5

GMDN Code(s): 58154

We herewith declare under our sole responsibility that the products specified above meet the
provisions of the above-mentioned Regulation. All supporting documentation is retained under the
premises of the manufacturer.

Conformity Assessment procedure acc. to Annex IV of the Regulation (EU) 2017/746.

Standards / common specifications:

Refer to the list of applicable (harmonized) standards and common specifications in the Technical
Documentation.

Kremsmünster, 24.03.2023



Georg Sambs
Quality Manager
Greiner Bio-One Austria

PRODUCT GROUP	Product name - detailed product description	Item numbers
MiniCollect® K3E K3EDTA TUBE	MiniCollect® TUBE 0.25/0.5 ml K3E K3EDTA lavender cap	450530
MiniCollect® K3E K3EDTA TUBE	MiniCollect® TUBE 1 ml K3E K3EDTA lavender cap	450531
MiniCollect® K3E K3EDTA TUBE	MiniCollect® Complete 0.25 / 0.5 ml K3E K3EDTA lavender cap, pre-assembled with Carrier Tube 13x75	450545
MiniCollect® K3E K3EDTA TUBE	MiniCollect® Complete 1 ml K3E K3EDTA lavender cap, pre-assembled with Carrier Tube 13x75	450546
MiniCollect® K3E K3EDTA TUBE	MiniCollect® Complete 1 ml K3E K3EDTA lavender cap, paper label, pre-assembled with Carrier Tube 13x75	450566
MiniCollect® K3E K3EDTA TUBE	MiniCollect® TUBE 0.25/0.5 ml K3E K3EDTA lavender cap, G-barcode label	480530
MiniCollect® K3E K3EDTA TUBE	MiniCollect® Complete 0.25 / 0.5 ml K3E K3EDTA lavender cap, barcode label, pre-assembled with Carrier Tube 13x75	480545
MiniCollect® K3E K3EDTA TUBE	MiniCollect® Complete 0.25 / 0.5 ml K3E K3EDTA lavender cap, G-barcode label, pre-assembled with Carrier Tube 13x75	480546