

EU-Konformitätserklärung EC Declaration of Conformity

Hiermit erklären wir in alleiniger Verantwortung, dass das unten beschriebene Produkt in der gelieferten Ausführung allen anwendbaren Bestimmungen der nachstehenden Richtlinie entspricht.

Herewith we declare under sole responsibility that the product described below as delivered is in compliance with all applicable assignments of the following directive.

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Produktname / Product Name	Art. Nr. / Art. No.
Mentype® DIPquant HLD101-D (25)	45-01501-0025
Mentype® DIPquant HLD101-D (50)	45-01501-0050
Mentype® DIPquant HLD101-I (25)	45-01502-0025
Mentype® DIPquant HLD101-I (50)	45-01502-0050
Mentype® DIPquant HLD103-D (25)	45-01505-0025
Mentype® DIPquant HLD103-D (50)	45-01505-0050
Mentype® DIPquant HLD103-I (25)	45-01506-0025
Mentype® DIPquant HLD103-I (50)	45-01506-0050
Mentype® DIPquant HLD104-D (25)	45-01507-0025
Mentype® DIPquant HLD104-D (50)	45-01507-0050
Mentype® DIPquant HLD104-I (25)	45-01508-0025
Mentype® DIPquant HLD104-I (50)	45-01508-0050
Mentype® DIPquant HLD105-D (25)	45-01509-0025
Mentype® DIPquant HLD105-D (50)	45-01509-0050
Mentype® DIPquant HLD105-I (25)	45-01510-0025
Mentype® DIPquant HLD105-I (50)	45-01510-0050
Mentype® DIPquant HLD106-D (25)	45-01511-0025
Mentype® DIPquant HLD106-D (50)	45-01511-0050
Mentype® DIPquant HLD106-I (25)	45-01512-0025

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Mentype® DIPquant HLD106-I (50)	45-01512-0050
Mentype® DIPquant HLD110-I (25)	45-01514-0025
Mentype® DIPquant HLD110-I (50)	45-01514-0050
Mentype® DIPquant HLD112-I (25)	45-01516-0025
Mentype® DIPquant HLD112-I (50)	45-01516-0050
Mentype® DIPquant HLD114-D (25)	45-01517-0025
Mentype® DIPquant HLD114-D (50)	45-01517-0050
Mentype® DIPquant HLD114-I (25)	45-01518-0025
Mentype® DIPquant HLD114-I (50)	45-01518-0050
Mentype® DIPquant HLD116-D (25)	45-01519-0025
Mentype® DIPquant HLD116-D (50)	45-01519-0050
Mentype® DIPquant HLD116-I (25)	45-01520-0025
Mentype® DIPquant HLD116-I (50)	45-01520-0050
Mentype® DIPquant HLD128-D (25)	45-01523-0025
Mentype® DIPquant HLD128-D (50)	45-01523-0050
Mentype® DIPquant HLD128-I (25)	45-01524-0025
Mentype® DIPquant HLD128-I (50)	45-01524-0050
Mentype® DIPquant HLD131-D (25)	45-01525-0025
Mentype® DIPquant HLD131-D (50)	45-01525-0050
Mentype® DIPquant HLD131-I (25)	45-01526-0025
Mentype® DIPquant HLD131-I (50)	45-01526-0050
Mentype® DIPquant HLD133-I (25)	45-01528-0025
Mentype® DIPquant HLD133-I (50)	45-01528-0050
Mentype® DIPquant HLD134-D (25)	45-01529-0025
Mentype® DIPquant HLD134-D (50)	45-01529-0050
Mentype® DIPquant HLD134-I (25)	45-01530-0025
Mentype® DIPquant HLD134-I (50)	45-01530-0050
Mentype® DIPquant HLD140-I (25)	45-01532-0025
Mentype® DIPquant HLD140-I (50)	45-01532-0050
Mentype® DIPquant HLD152-D (25)	45-01533-0025
Mentype® DIPquant HLD152-D (50)	45-01533-0050
Mentype® DIPquant HLD163-D (25)	45-01535-0025
Mentype® DIPquant HLD163-D (50)	45-01535-0050

Produktname / Product Name	Art. Nr. / Art. No.
Mentype® DIPquant HLD163-I (25)	45-01536-0025
Mentype® DIPquant HLD163-I (50)	45-01536-0050
Mentype® DIPquant HLD23-I (25)	45-01538-0025
Mentype® DIPquant HLD23-I (50)	45-01538-0050
Mentype® DIPquant HLD301-D (25)	45-01539-0025
Mentype® DIPquant HLD301-D (50)	45-01539-0050
Mentype® DIPquant HLD301-I (25)	45-01540-0025
Mentype® DIPquant HLD301-I (50)	45-01540-0050
Mentype® DIPquant HLD304-D (25)	45-01541-0025
Mentype® DIPquant HLD304-D (50)	45-01541-0050
Mentype® DIPquant HLD305-D (25)	45-01543-0025
Mentype® DIPquant HLD305-D (50)	45-01543-0050
Mentype® DIPquant HLD305-I (25)	45-01544-0025
Mentype® DIPquant HLD305-I (50)	45-01544-0050
Mentype® DIPquant HLD307-D (25)	45-01545-0025
Mentype® DIPquant HLD307-D (50)	45-01545-0050
Mentype® DIPquant HLD307-I (25)	45-01546-0025
Mentype® DIPquant HLD307-I (50)	45-01546-0050
Mentype® DIPquant HLD310-D (25)	45-01549-0025
Mentype® DIPquant HLD310-D (50)	45-01549-0050
Mentype® DIPquant HLD38-I (25)	45-01558-0025
Mentype® DIPquant HLD38-I (50)	45-01558-0050
Mentype® DIPquant HLD48-I (25)	45-01560-0025
Mentype® DIPquant HLD48-I (50)	45-01560-0050
Mentype® DIPquant HLD53-D (25)	45-01561-0025
Mentype® DIPquant HLD53-D (50)	45-01561-0050
Mentype® DIPquant HLD53-I (25)	45-01562-0025
Mentype® DIPquant HLD53-I (50)	45-01562-0050
Mentype® DIPquant HLD67-D (25)	45-01567-0025
Mentype® DIPquant HLD67-D (50)	45-01567-0050
Mentype® DIPquant HLD67-I (25)	45-01568-0025
Mentype® DIPquant HLD67-I (50)	45-01568-0050
Mentype® DIPquant HLD70-D (25)	45-01569-0025

Produktname / Product Name	Art. Nr. / Art. No.
Mentype® DIPquant HLD70-D (50)	45-01569-0050
Mentype® DIPquant HLD70-I (25)	45-01570-0025
Mentype® DIPquant HLD70-I (50)	45-01570-0050
Mentype® DIPquant HLD79-I (25)	45-01576-0025
Mentype® DIPquant HLD79-I (50)	45-01576-0050
Mentype® DIPquant HLD82-D (25)	45-01577-0025
Mentype® DIPquant HLD82-D (50)	45-01577-0050
Mentype® DIPquant HLD82-I (25)	45-01578-0025
Mentype® DIPquant HLD82-I (50)	45-01578-0050
Mentype® DIPquant HLD84-D (25)	45-01579-0025
Mentype® DIPquant HLD84-D (50)	45-01579-0050
Mentype® DIPquant HLD84-I (25)	45-01580-0025
Mentype® DIPquant HLD84-I (50)	45-01580-0050
Mentype® DIPquant HLD88-D (25)	45-01581-0025
Mentype® DIPquant HLD88-D (50)	45-01581-0050
Mentype® DIPquant HLD88-I (25)	45-01582-0025
Mentype® DIPquant HLD88-I (50)	45-01582-0050
Mentype® DIPquant HLD91-D (25)	45-01585-0025
Mentype® DIPquant HLD91-D (50)	45-01585-0050
Mentype® DIPquant HLD91-I (25)	45-01586-0025
Mentype® DIPquant HLD91-I (50)	45-01586-0050
Mentype® DIPquant HLD97-I (25)	45-01588-0025
Mentype® DIPquant HLD97-I (50)	45-01588-0050
Mentype® DIPquant SMCY (25)	45-01589-0025
Mentype® DIPquant SMCY (50)	45-01589-0050
Mentype® DIPquant SRY (25)	45-01590-0025
Mentype® DIPquant SRY (50)	45-01590-0050
Mentype® DIPquant Reference (25)	45-01591-0025
Mentype® DIPquant Reference (50)	45-01591-0050
Mentype® DIPquant Reference (100)	45-01591-0100

Produktbezeichnung

Quantitative Polymerasekettenreaktion in Echtzeit zur Chimärismusüberwachung nach Blutstammzell- oder Knochenmarktransplantation

Konformitätsbewertungsverfahren

Richtlinie 98/79/EG für In-vitro-Diagnostika (IVDD), Anhang III, Satz 1 - 5

Klassifizierung

sonstige

Gültigkeitsdauer

25.05.2025

Die Produkte sind mit dem CE-Kennzeichen versehen.

Product description

Real-time quantitative polymerase chain reaction for chimerism monitoring after blood stem cell or bone marrow transplantation

Conformity assessment procedure

Directive 98/79/EC on in vitro diagnostic medical devices (IVDD), Annex III, section 1 - 5

Classification

other

Validity

25.05.2025

The products are CE marked.

Dresden, 03.05.2022

The CE mark, consisting of the letters "C" and "E" in a stylized, bold font.A handwritten signature in blue ink, appearing to read "Dr. Norman Gerstner".

Dr. Norman Gerstner
Geschäftsführer/CEO