

Declaration of Conformity
in accordance with annex II of the Council Directive 93/42/EEC concerning medical devices

We, P.J. Dahlhausen & Co. GmbH, Emil-Hoffmann-Str. 53, 50996 Cologne, declare that our medical devices specified below meet the provisions of the Council Directive 93/42/EEC concerning medical devices which apply to them:

REF	Description
01.000.08.752	nebulizer kit, ped., mask, 6ml nebuliz. chamber, 210 cm tube, universal/standard connector
01.000.08.753	nebulizer kit, adult, mask, 6ml nebuliz.chamber, 210 cm tube, universal/standard connector
01.000.08.852	nebulizer kit, ped., mask, 6ml nebuliz. chamber, 210 cm tube, standard connector both sides
01.000.08.853	nebulizer kit, adult, mask, 6ml nebuliz.chamber, 210 cm tube, standard connector both sides
01.000.08.900	nebulizer kit, adult, mouthpiece,T-pcs, 6ml nebuliz. chamber, 210 cm tube, standard connector
01.000.08.901	nebulizer kit, adult, mouthpiece,T-pcs, 6ml nebuliz. chamber, 210 cm tube, 15cm corrugated tube
01.000.08.903	nebulizer kit, adult, for breathing circuits, 6ml nebuliz. chamber, T-piece, 210 cm tube
01.000.08.904	nebulizer kit, adult, for breathing circuits, 6ml nebuliz. chamber, valve, 210 cm tube
01.000.08.905	nebulizer therapy system, adult, T-pcs, 6ml nebuliz. chamber, non-return valve, 210 cm tube, 2 stand. conn.
01.000.08.906	nebulizer therapy system, adult, T-pcs, 6ml nebuliz. chamber, non-return valve, 210 cm tube, 1 stand./1 soft connector
01.000.08.910	nebulizer kit, adult, mouthpiece,T-pcs, 20ml nebuliz. chamber, 210 cm tube, standard connector
01.000.08.914	nebulizer kit, adult, mouthpiece,T-pcs, 20ml nebuliz. chamber
01.000.08.915	nebulizer kit, adult, mouthpiece,T-pcs, 20ml nebuliz. chamber, 210 cm tube and aerosol tube
01.000.08.921	nebulizer kit, ped., mask, 20 ml nebuliz.chamber, 210 cm tube, standard connector
01.000.08.924	nebulizer kit, adult, mask, 20 ml nebuliz.chamber, 210 cm tube, universal/standard connector
01.000.08.925	nebulizer kit, adult, mask, 20 ml nebuliz.chamber, 210 cm tube w. stand. con.
01.000.09.100	nebulizer therapy closed sys adult, mouthp., 6 ml nebuliz. chamber, ex./insp. valve, filter, 210 cm tube, 2 stand. conn.

Medical device class IIa

The declaration is based on the EC-Certificate issued by the TÜV Süd Product Service GmbH, Ridlerstr. 65, 80339 Munich (notified body no. 0123) in accordance with Annex II of the Council Directive 93/42/EEC concerning medical devices of 14th June 1993.

Our quality system is based on the requirement of the EN ISO 13485 and is approved by the TÜV Süd Product Service GmbH.

We hereby declare the sole responsibility for the issuing of this Declaration of Conformity.

This declaration is valid until May 19, 2023.

Cologne, 25 May 2018