



# Certificate

No. Q6 074352 0009 Rev. 00

**Holder of Certificate:** **Fisher & Paykel Healthcare S.A. de C.V.**  
Ave. Todos Los Santos 12831  
Parque Industrial Pacifico  
22643 Tijuana, Baja California  
MEXICO

**Facility(ies):** Fisher & Paykel Healthcare S.A. de C.V.  
Ave. Todos Los Santos 12831, Parque Industrial Pacifico, 22643  
Tijuana, Baja California, MEXICO  
  
Fisher & Paykel Healthcare S.A. de C.V.  
Blvd. La Encantada No. 24352-A, Colonia Fideicomiso El Florido,  
22245 Tijuana, Baja California, MEXICO

**Certification Mark:**



**Scope of Certificate:** **Production and Distribution of Nasal and/or Oral Interfaces for Delivery of Respiratory Gases, and Respiratory Gas Delivery Systems**

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 72159739

**Valid from:** 2020-05-11

**Valid until:** 2022-09-29

**Date,** 2020-05-11

Christoph Dicks  
Head of Certification/Notified Body