S.I.I.T. S.R.L. - UNIPERSONALE
PHARMACEUTICAL & DIETETIC CONTRACT MANUFACTURING
SOGGETTA A DIREZIONE E COORDINAMENTO DA DICIANNOVE HOLDING S.R.L.

DECLARATION OF CONFORMITY

The company S.I.I.T srl, located at Trezzano sul Naviglio, via Ariosto 50/60, as producer of the Medical device

HUMER TOUX

declares under its own responsability that the Medical device object of this declaration satisfies the dispositions of **Law Decree 24 February 1997, N° 46**, (Directive 93/42/CEE on Medical devices) and subsequent amendments and additions (Implementation of Directive 93/42/EEC and subsequent amendments concerning the CE marking Medical Devices)

We declare that:

- The Medical device satisfies the requisites specified in Enclose I of Law Decree 24 February 1997, N° 46
- The Medical device is classified as **CLASS IIA**, invasive in natural orifice, of short term use, following criteria of classification specified in **Enclose IX, rule 5** - Law Decree 24 February 1997, N° 46
- Destination of use is **treatment of dry and productive cough, and protecting mucosae**
- The Medical device is commercialized in NON STERILE packaging
- The Medical device is NOT MEASURE DEVICE
- The Medical device is not to be used for CLINICAL INVESTIGATIONS
- The Medical device is commercialized with the mark CE as specified in art. 16 of Law Decree 24 February 1997, N° 46 and is manufactured according to the Quality Management System that meets the requirements of Annex V and VII to Directive 93/42/EEC and subsequent amendments, in accordance with a certificate issued by ITALCERT (ON 0426) in force at the date of this declaration

The Qualified person

Dr.ssa Fabrizia Costa

Trezzano s/N (MI), printed on 10 December 2018