

Declaration of Conformity

We declare under our own responsibility, that the Medical Devices

Condoms

of class IIb according to MDD 93/42/EEC, annex IX, rule 14
as described in enclosed Annex 1

meet all requirements of the Medical Device Directive 93/42/EEC
updated by MDD 2007/47/EC which apply to it.

Applied harmonised standards, national standards or other normative documents:

EN ISO 4074:2015
DIN EN ISO 15223-1:2017
EN 1041:2008, A1:2013
EN ISO14971:2012

Conformity assessment procedure :

Annex II, with exception of requirements of Annex II, Article 4

Notified Body:

MEDCERT Zertifizierungs- und Prüfgesellschaft für Medizin GmbH
registered with number 0482
Pilatuspool 2, D-20355 Hamburg

The technical file is established and may be seen by the national authorities
and notified bodies if required.

Erfurt, 24.08.2020


M. Kesselring
Managing Director

PREVENTIVO - CONDOMS

preventivo feelings 24 pcs.

preventivo moments 24 pcs.

preventivo sensation 3 pcs.

preventivo sensation 24 pcs.

preventivo sensitive 1 pcs.

preventivo sensitive 3 pcs.

preventivo sensitive 12 pcs.

preventivo sensitive NP 12 pcs.

preventivo sensitive 24 pcs.

preventivo sensitive 50 pcs.

preventivo XXL Size 24 pcs.

preventivo mixed 24 pcs.

consisting of

preventivo feelings

preventivo moments

preventivo perfect size

preventivo sensitive

preventivo sensation

preventivo strawberry

preventivo banana

preventivo Colour Fantasy Mix 12 pcs.

consisting of

preventivo sensitive

preventivo strawberry

preventivo banana

preventivo raspberry

Applied Batch number and number of items:

as recorded in our LIMS

and

Win Line