

Declaration of Conformity

in accordance to the EC – Directive 93/42/EWG from June 14th 1993 of Medical Devices (MDD)

The manufacturer

BHT Hygienetechnik GmbH
Messerschmittstraße 11
D-86368 Gersthofen

declares herewith, that the machines

Designation : Industrial cleaner for endoscopes
Type of machine : Innova E2

correspond to the essential requirements of the MDD, especially to appendix I and II, and they correspond to the following standards and normative documents :

Safety requirements :

EN 61010 – 1 : 1993 + A2 : 1995
IEC 1010 – 1 : 1990 + A1 : 1992 + A2 : 1995

Safety Requirements for electrical equipment for measurement, control and laboratory use.

Electromagnetic compatibility (EMC) :

IEC 60 601 – 1 – 2 : 1993

Medical electrical equipment
Part 1 : General requirements for safety,
2. Collateral standard : Electromagnetic compatibility – Requirements and tests.

DVGW (Deutscher Verein des Gas – und Wasserfaches e.V.) :

DVGW W 507 : 1990

DVGW – registration certificate for equipment of water alimentation, washing machines for commercial purposes at Not - foods array up to PN 10.

Gersthofen, 01.07.03

Place, date


Dr. Annecke
Managing director


Mr. Lautenbacher
Safety/commissioner of medical devices