

Declaration of Conformity

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

The manufacturer

BHT Hygienetechnik GmbH
Messerschmittstraße 11
D-86368 Gersthofen

declares herewith, that the machines

Designation : Disinfection, cleaning and drying machine for medical wash goods
Type of machine : INNOVA E3, M3

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 :

IEC 601-1 : 1988 + A1 : 1991 + A2 : 1995 Medical electrical equipment
Part 1 : General requirements for safety

Electromagnetic compatibility (EMC) :

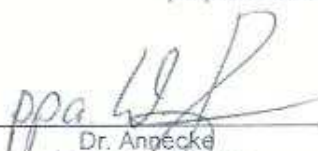
EN 60 601-1-2 : 1994 Medical electrical equipment
Part 1 : General requirements for safety,
2. Collateral standard : Electromagnetic compatibility – Requirements and tests.

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. Anpecke
Managing director


i. A. Lauthbacher
Mr. Lauthbacher
Safety commissioner of
medical devices