【P-03】[様式 13]改 3

MANI, INC.

Declaration of Conformity

Name and address of the firm

MANI, INC.
8-3 Kiyohara Industrial Park, Utsunomiya, Tochigi, 321-3231, Japan

Manufacturing site

MANI, INC. Takanezawa Factory
743, Nakaakutsu, Takanezawa, Tochigi, 329-1234, Japan

MANI HANOI CO., LTD. Pho Yen Factory
Tan Huong Commune, Pho Yen Town, Thai Nguyen Province,
Viet Nam

We declare under our sole responsibility that the Medical device

Product Group / Dental Endodontic Instruments
Product Names / MANI GATES DRILLS
Product Types / #1, #2, #3, #4, #5, #6

of class and rule

Class II a , Rule 6,Subclause 1,No indent
according to annex IX of direct. 93/42/EEC

meets all the provisions of the directive 93/42/EEC which apply to it.

Applied harmonised standards, national standards or other normative documents

EN ISO 13485:2016, EN ISO 13485:2016/AC:2018, EN ISO 14971:2012,
EN ISO 10993-1:2009, EN ISO 10993-1:2009/AC:2010,
EN ISO 10993-5:2009, EN ISO 10993-10:2010,
EN ISO 7405:2008, EN 1041:2008, EN ISO 15223-1:2016,
IEC 62366:2007, EN 62366:2008, EN ISO 17664:2004, ISO 3630-2:2013,
ISO 1797-1:2011, ISO 1797-1:2011/A1:1997, EN 1639:2009, EN 1640:2009

;[

Conformity assessment procedure

EC Directive 93/42/EEC Annex II , excluding Section 4
Full Quality Assurance System
Medical Devices
TUV Rheinland LGA Products GmbH
Registration No. HD 60142912 0001

Notified Body

TUV Rheinland LGA Products GmbH (Notified Body 0197)
Tillystr. 2, 90431 Nürnberg Germany

EU Authorized Representative

Obelis s.a.
Bd. Général Wahis 53, 1030 Brussels
Belgium

This DOC is effective in relation to the manufacturing instruction for each lot of manufactured products.

Tochigi, Japan
2020-08-31

Management Representative
Toshiyuki Takase

Place, date | Name and function

DOC No. 1490502-14