



Declaration of no objection

WALDEMAR LINK GMBH Co. KG
Barkhausenweg 10
22339 Hamburg

Hereby confirms that, to the best of our knowledge, the medical devices of the below mentioned prostheses systems represent no harms or unacceptable risks during MRI examinations using a 3.0 T scanner.

SP II[®] Model Lubinus

Ribbed System

C.F.P.[®] Hip Stem

BetaCone[™] Prosthesis Stem

T.O.P.[®] acetabular Cup System

BetaCup[®] cementless acetabular Cup System

Cementable UHMWPE Hip Cups

CoCrMo Prosthesis Head (Prosthesis Head B)

Endo-Model[®] Partial Pelvis Replacement

S.T.A.R.[®] Scandinavian Total Ankle Replacement

However, it is within the decision and responsibility of the physician whether an MRI examination shall be performed or not.

11. May 2009,

Thomas Greiner

Manager, Regulatory Affairs