

EC Declaration of Conformity

Manufacturer:

Ortho Pauher Ind. Com. E Dist. Ltda.
Rua Bandeirantes, 94 - Afogados
Recife - Pernambuco-Brasil - 50770-460

whose single Authorized Representative:

Obelis S.A.
Boulevard Général Wahis 53, 1030 Schaerbeek,
Belgium

We, the manufacturer, herewith declare that the product

Prostheses, Mammary, External
Models: 1050, 1052, 1054, SG419, SG420

UMDNS-Code: 16-112

meets the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC. It bears the mark



The product concerned has been manufactured according to Annex VII of Directive 93/42/EEC.

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC.

The above mentioned declaration of conformity is exclusively under the responsibility of

Ortho Pauher Ind. Com. E Dist. Ltda.

Recife, Brazil, May. 3, 2016

Henrique Queiroz - General Manager