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Declaration of Conformity for Medical Devices

We hereby declare that the products specified in the attached product list meet the relevant provisions of the European Medical Device Directive 93/42/EEC.

In addition we ensure and declare that the distributed CE marked products as mentioned and falling within Class I, meet the provisions of the CE-directive which apply to them.

This declaration is based on the application of the Quality System approved for the manufacture and final inspection of the products concerned.

This declaration is supported by the Quality System certification based on the standards ISO 9001:2008, Quality System Certificate with reference number 14639-A issued on 26 february 2008 and ISO 13485:2003, Quality System Certificate with reference number 14639-M issued on 26 february 2008 and delivered by Kiwa Cermet Italia S.p.A..

This declaration of Conformity covers the CE marked products specified on the attached product list and manufactured at the following site.

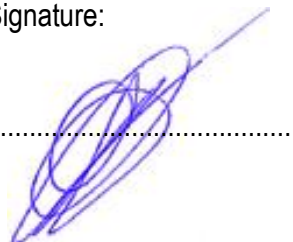
MediTop BV
Vlasakker 22
3417 XT Montfoort
The Netherlands

G.P. van Breukelen

Signature:

Montfoort, 1 December 2015

Attached: Product List



Attachment to Declaration of Conformity

Product List Exsudex Canisters

Annex to Declaration of Conformity

This product list belongs to the declaration of conformity issued by MediTop BV and specifies the CE marked products concerned that MediTop BV intends to distribute in conformity with the provisions of the council directive 93/42/EEC

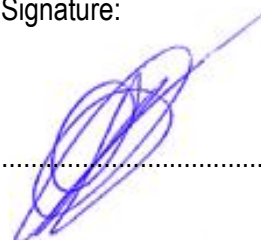
The following list identifies the products by name and Productcode.

Name of the product	Product code
Exsudex W1/XL Disposable canister, 900 cc with filter and sterile tube.	16670
Exsudex W1/XL Disposable canister, 900 cc with filter.	16670-HZS
Exsudex W1/XL Disposable canister, 900 cc with filter and fixed unsterile tube.	16670-LL
Exsudex W1/XL Disposable canister, 900 cc with filter and fixed unsterile tube.	16670-HAROMED
Exsudex W1/XL Disposable canister, 500 cc with filter and sterile tube.	16671
Exsudex W1/XL Disposable canister, 500 cc with filter.	16671-ZSLANG
Exsudex W1/XL Disposable canister, 500 cc with filter and fixed unsterile tube.	16671-LL
Exsudex W1/XL Disposable canister, 500 cc with filter and fixed unsterile tube.	16671-HAROMED
Exsudex XS Disposable canister, 300 cc with filter and fixed unsterile tube.	16690
Exsudex XS Disposable canister, 300 cc with filter.	16690-ZSLANG
Exsudex XS Disposable canister, 300 cc with filter and fixed unsterile tube.	16690-LL
Exsudex XS Disposable canister, 300 cc with filter and fixed unsterile tube.	16690-HAROMED

G.P. van Breukelen

Signature:

Montfoort, 1 December 2015


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