Dear Mr. Savic,

After several consultations with the notified body in the Netherlands, I can inform you as follows. The notified body in the Netherlands has informed me that it does not consider the marker test to be an in vitro diagnostic medical device. Unfortunately, the notified body is not willing to render a written opinion about this issue.

Together with the notified body, I have discussed that the marker test must meet the definition of an in vitro diagnostic medical device as well as that of a medical device.

In vitro diagnostic medical device
As you know, an in vitro diagnostic medical device is a medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

– concerning a physiological or pathological state, or

– concerning a congenital abnormality, or

– to determine the safety and compatibility with potential recipients, or

– to monitor therapeutic measures.

The following shall also be regarded as in vitro diagnostic medical devices:

– specimen receptacles;

– products for laboratory use that, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

In vitro diagnostic medical device a medical device
From the definition of an in vitro diagnostic medical device it follows that in order to fall within the definition of an in vitro diagnostic medical device, the product must also meet the definition of a medical device. A medical device means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

– diagnosis, prevention, monitoring, treatment or alleviation of disease,

– diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

Jachthavenweg 121
1081 KM Amsterdam
P.O. Box 75265
1070 AG Amsterdam

T +31 (0) 20 6789 406
F +31 (0) 20 7954 406
M +31 (0) 6 52 366 583
The Netherlands

rdijkstra@van-doorne.com

www.van-doorne.com

– investigation, replacement or modification of the anatomy or of a physiological process,

– control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Marker test
Based on the information you have provided to us, together with the notified body I have reached the conclusion that taking into account the purpose for which the marker test is used – merely matching a urine sample to the person tested – Ruma does not have to notify the notified body in the Netherlands. Ruma must of course refrain from offering the marker test for the purposes described in the definitions of an in vitro medical device and a medical device.

Should you have any further questions or comments, please do not hesitate to contact me.

Kind regards,

Ricardo

Van Doorne N.V.
Ricardo Dijkstra
Advocaat

Jachthavenweg 121
1081 KM Amsterdam
P.O. Box 75265
1070 AG Amsterdam

T +31 (0) 20 6789 406
F +31 (0) 20 7954 406
M +31 (0) 6 52 366 583
The Netherlands

rdijkstra@van-doorne.com

www.van-doorne.com