Agreement

Willmann & Pein GmbH
Schusterring 35
25355 Barmstedt
Germany

and

Vivodent
Centrul Stomatologic
Str. Bucuresti 13/1
2001 Mun. Chisinau
Republic of Moldova

Have agreed as follow, regarding the safe handling of the medical devices (hereinafter called "Products") manufactured and supplied by Willmann & Pein GmbH to Vivodent Centrul Stomatologic in order to comply with the requirements of the Government Decision no.418 of 05 June 2014 concerning Medical Devices (GDMD) and the "Guidelines on a Medical Devices Vigilance System".

Semnătura Semnătă Alexandru
Date: 2022.08.26 12:05:01 EEST
Reason: MoldSign Signature
Location: Moldova

APPOINTMENT

Willmann & Pein GmbH hereby appoints Vivodent Centrul Stomatologic upon the terms and conditions herein contained to be official representative for the products manufactured by Willmann & Pein GmbH.

And whereas Vivodent Centrul Stomatologic expresses their desire to into an agreement with Willmann & Pein GmbH upon the terms and conditions set forth in this Agreement.

RESPONSIBILITIES OF BOTH PARTIES - GENERAL INFORMATION

Vivodent Centrul Stomatologic is authorized to perform registration, renewal, variation of the registration.
Willmann & Pein GmbH shall provide to Vivodent Centrul Stomatologic for the registration of medical devices the following information:

) Declaration of conformity,
b) Copy of the label, packaging and instructions for use (in all languages requested by the countries where the device is marketed),
c) Notified Body certificates (where relevant),
d) Post market surveillance process and data, vigilance reports and complaints, processes and data,
e) Technical documentation relevant to market surveillance investigation being undertaken by the Medicines and Medical Devices Agency (Agency),
f) Relevant clinical data/notification,
g) Details of any distributors/suppliers putting the Republic of Moldova marked devices on the market,
h) Incident reports and reports on corrective actions taken.

Vivodent Centrul Stomatologic shall be responsible for registration, monitoring and to communicate all claims for the customers and market related of the products of Willmann & Pein GmbH and to notify Willmann & Pein GmbH upon receiving such claims.

Incident Reporting

Vivodent Centrul Stomatologic shall maintain an update Quality System and communicate the vigilance procedures to Willmann & Pein GmbH for coordination and continuity of Willmann & Pein GmbH own Quality System. Vivodent Centrul Stomatologic shall communicate any of other procedures upon request of the Willmann & Pein GmbH.
Vivodent Centrul Stomatologic shall work closely with Willmann & Pein GmbH and shall transmit without delay any information coming from the Agency. In case of special request by the Agency, particularly in relation with incidents reporting, the Vivodent Centrul Stomatologic will agree with Willmann & Pein GmbH on the position statement and answers to give to the Agency.
In case of difference in positions between Willmann & Pein GmbH and Vivodent Centrul Stomatologic, the position of Willmann & Pein GmbH will prevail and will be supplied to the Agency with a format endorsement of the Willmann & Pein GmbH. Vivodent Centrul Stomatologic shall have a qualified person to be in contact with the Agency.

In case of incidents known first by the Willmann & Pein GmbH, the Vivodent Centrul Stomatologic will be immediately informed and will immediately perform with the Willmann & Pein GmbH the analysis of the accident. Vivodent Centrul Stomatologic will write and send to the concern Agency the initial report including Willmann & Pein GmbH actions if available such as sample analysis, analysis of historic lot record and potential corrective actions to be taken in the further manipulation of the product like withdraw, recall from the market.

dent Centrul Stomatologic shall notify Agency about the following time lines apply in a e of:

a) Serious public health threat: IMMEDIATELY (without any delay that could not be justified) but not later than 2 calendar days after awareness by the Willmann & Pein GmbH of this threat.
b) Death or UNANTICIPATED serious deterioration in state of health: IMMEDIATELY (without any delay that could not be justified) after the Willmann & Pein GmbH established a link between the device and the event but not later than 10 elapsed calendar days following the date of awareness of the event.
c) Others: IMMEDIATELY (without any delay that could not be justified) after the Willmann & Pein GmbH established a link between the device and the event but not later than 30 elapsed calendar days following the date of awareness of the event.

If after becoming aware of a potential reportable INCIDENT there is still uncertainty about whether the event is reportable, Willmann & Pein GmbH must submit a report with the timeframe required for the type of INCIDENT.

As soon as information and incidents assessment from Willmann & Pein GmbH are available, Vivodent Centrul Stomatologic writes and sends the final incidents report. In any case, Vivodent Centrul Stomatologic submits these reports to Willmann & Pein GmbH for preliminary approval. Vivodent Centrul Stomatologic will keep these records available for the Agency.

According to the stipulation of medical equipment plant GDMD, the Willmann & Pein GmbH must summarize the experience of manufacturing products, take proper measures, and have the right to know the incident occasionally happened, and take proper measures.

a) The mangle of property of medical equipment, improper logo, and misuse without the guide of instruction for use can lead to lead to the death of patients and users and deterioration of health condition.
b) The above-mentioned, the technical property of the products or the problems in medicine, the company has the right to recall the products of the same lot and specification.

Field safety notice

The Willmann & Pein GmbH finds that there is a problem of quality of the products on the market, it should immediately give out a Field Safety Notice for the users, so they could be able to take the necessary measures (including the recall of the products).

of products are withdrawn from the market, the Willmann & Pein GmbH should the products immediately. Before recalling the products, Vivodent Centrul atologic should inform the Agency.

rn the products to the company

mann & Pein GmbH shall send advisory notice to Vivodent Centrul Stomatologic in this gion and order him to cease selling the products. Recall the products sold to the market r inform the users, ask the Vivodent Centrul Stomatologic in this region to inform the local governing department where the products are sold.

After the Vivodent Centrul Stomatologic recalls the products, Willmann & Pein GmbH should agree with the Vivodent Centrul Stomatologic on the mode of transportation or time, and return the products to the company for disposal.

Traceability of Sold Products

Willmann & Pein GmbH shall keep records of serial numbers, batch numbers for all products delivered to Vivodent Centrul Stomatologic.

Vivodent Centrul Stomatologic shall keep records of the Products delivered to the users or distributors. In this case the traceability of sold products can be performed at any time upon request. Records shall include the following information:

Name and address of the customer

Quantity dispatched

Date transferred to the customer

Serial or production lot numbers

It is agreed that these records should be available for inspection upon request by Willmann & Pein GmbH or by the relevant authorities.

Technical Documentation

Willmann & Pein GmbH shall establish necessary procedures to prepare and maintain Technical Documentation including the Declaration of Conformity for the products manufactured by Willmann & Pein GmbH to be able to comply with the GDMD requirements.

Willmann & Pein GmbH shall transfer the agreed Technical documentation and Declaration of Conformity to Vivodent Centrul Stomatologic

Vivodent Centrul Stomatologic shall keep the Technical Documents including the Declaration of Conformity available to the Agency for at least five years after the last products has been sold.

mann & Pein GmbH shall provide Vivodent Centrul Stomatologic and additional cumentation if required by Agency.

Terms of payment:
30 days net after date of invoice.

Instruction Manual
Willmann & Pein GmbH shall be responsible for content of instructions manual (user's guide) and shall ensure the availability of the English version of the instructions manual for Vivodent Centrul Stomatologic.
Vivodent Centrul Stomatologic shall ensure the required instruction manuals to be provided to the customer in official language of the Republic of Moldova.

For the following Product Categories:
product group and models/types

WP4010	P-Cem
WP4050	Extra-Gel, 1 x 2 ml
WP4051	Extra-Gel, 2 x 2 ml
WP4110	Securafix
WP4190	Competence Flow, A2
WP4191	Competence Flow, A3
WP4192	Competence Flow, A3,5
WP4196	Competence Flow, B2
WP4197	Competence Flow, Set
WP4200	Calcident 450, 1 x 2 ml
WP4201	Calcident 450, 2 x 2 ml
WP4230	C-Bond, 10 ml
WP4250	Competence universal, Set B2
WP4251	Competence universal, Set C2
WP4252	Competence universal, A1
WP4253	Competence universal, A2
WP4254	Competence universal, A3
WP4255	Competence universal, A3,5
WP4256	Competence universal, B2
WP4257	Competence universal, C2
WP4258	Competence universal, D3
WP4259	Competence universal, A3 opaque

[illegible]	Competence universal, A2 opaque
[illegible]1	Competence universal, Incisal
[illegible]0	Calcident LC, 2 x 2 ml
[illegible]71	Calcident LC, 1 x 2 ml
[illegible]311	Dent-a-cav, pink
[illegible]312	Dent-a-cav, white
[illegible]4913	Vision Prophy Powder, black-raspberry
[illegible]P4914	Vision Prophy Powder, mint
[illegible]P5001	Plaque Photo, upper pink
WP5001A	Plaque Photo, lower pink
WP5601	Glass Liner, 1 x 2 ml
WP5602	Glass Liner, 2 x 2 ml
WP6139	Vision Prophy Paste, strawberry
WP6140	Vision Prophy Paste, lemon

Mr. Joachim Pein	Barmstedt,	
-President-	Place, Date	Signature

Mr. Alexandru Smintina		
-President-	Place, Date	Signature

ub/willmann&pein-moldau

Nummer 189 der Urkundenrolle aus 2015

Die umstehende, heute vor mir vollzogene Namensunterschrift

des Herrn Joachim Pein
geb. am 14.10.1950
Geschäftsanschrift: Schusterring 35, 25355 Barmstedt
- dem Notar von Person bekannt -

beglaubige ich hiermit notariell.

Der Erschienene erklärte auf Befragen, dass der Notar in der Angelegenheit, die Gegenstand dieser Beurkundung ist, nicht außerhalb seines Notaramtes tätig war oder ist.

Barmstedt, den 16. Juni 2015

-Notar-

Kostenvermerk:

Gebühr
gem. Nr. 1310 GV
JVKostG

20,00 €

Die Echtheit vorstehender Unterschrift des

Notars Dr. Burkhard Wehleit
in Barmstedt

und die Echtheit des beigefügten Dienststempels (Dienstsiegels) wird hiermit beglaubigt.

Zugleich wird bescheinigt, dass der Vorgenannte zur Vornahme der Amtshandlung befugt war.

Itzehoe, 22. Juni 2015
Der Präsident des Landgerichts Itzehoe

Dr. Bernhard Flor

Dr. Bernhard Flor
Präsident des Landgerichts Itzehoe